Public Health Programme 2003 - 2008

Final Technical Implementation Report

Grant agreement n°. 2003208

Action: "JACIE"

1. Detailed description of activities conducted

This description of the activities conducted is structured in accordance with the outputs indicated in **1.4 of Annex 1 – Description of the Action** and as detailed in the **Overview of deliverables, internal/external monitoring and completion/acceptance criteria** submitted as part of the project management documentation (a copy of which is included in the supporting documentation and on the "JACIE project" CD Rom submitted with this report).

Late signature of the contract agreement, due to changes within the Commission, meant that a number of deliverables could not be produced according to the original schedule, particularly those related to the development of the JACIE Online system. The project timeframe was extended by two months to accommodate this and the majority of the deliverables of the project were met within the project timeframe 1 January 2004 to 28 February 2005.

A. Harmonisation and promotion of standards

Deliverable 1	**Development of quality measures and standards in specific areas**
Work packages	**1.1** Harmonisation of 2nd edition of JACIE Standards with the EU Directive on standards for quality and safety of human tissues and cells

One of the main aims of the "JACIE" project was to ensure the integral role of the JACIE accreditation programme in standard setting, inspection and accreditation of health facilities involved in haematopoietic stem cell collection, processing and transplantation (HSCT) in Europe. In order to achieve this it was important that the JACIE Standards and programme of accreditation be developed in-line with the requirements of the EU Directive on standards for quality and safety of human tissue cells. JACIE would thereby be in a position to contribute to the implementation of the Directive, offering Member States a set of Standards and programme of accreditation fulfilling the EU requirements and contributing to harmonisation across Europe.

At the outset of the project EU legislation was imminent (Proposal COM (2003) 319 final) and this resulted in EU Directive 2004/23/EC, which was published in the Official Journal of the European Union on 31 March 3004. Over the course of 2004 and 2005 the Commission has worked on developing two technical annexes to the Directive and has involved leading experts and key stakeholders in the process.

The 2nd edition of the JACIE Standards was under development at the same time and the **objective was to produce a 2nd edition in line with the requirements set out in the technical annexes to the Directive.**

In order to achieve this JACIE personnel were appointed at the beginning of 2004 to represent JACIE vis-à-vis the Commission with regard to the elaboration of EU Directive 2004/23/EC and associated technical annexes:
- Dr. Alvaro Urbano-Ispizua, JACIE President
- Dr. Ineke Slaper-Cortenbach, JACIE Vice President

JACIE has been involved in the whole EU consultation process to develop the EU Directive and technical annexes, through JACIE personnel acting as private experts and JACIE providing official input into the public consultation process.

JACIE was represented at the following meetings organised by Eduardo Ferněndez Zincke from the Directorate-General Health and Consumer Protection at the European Commission:

1. Discussion of the technical requirements of the Tissues and Cells Directive (meeting with private experts), Luxembourg, 15 March 2004 (attended by Dr. Alvaro Urbano-Ispizua).

2. Discussion of the second set of technical requirements (coding, processing, preservation, storage and distribution) under Directive 2004/23/EC, Brussels, 23 November 2004 (attended by Dr. Ineke Slaper-Cortenbach).

These meetings contributed to the development of the first and second set of technical annexes to the Directive which were opened for Public Consultation in October 2004 and May 2005 respectively. JACIE Board members were asked to comment on the technical annexes and Dr Ineke Slaper Cortenbach submitted official feedback on behalf of the Joint Accreditation Committee of ISCT and EBMT on 1 October 2004 and 24 June 2005 respectively. Copies of this official feedback are included in the appendices to this report (WP 1.1: Second edition of JACIE Standards in line with EU Directive). All EBMT members (1800 physicians, nurses and data managers working in HSCT facilities across Europe) were sent emails by the JACIE Office inviting them to comment on the technical annexes within the public consultation process.

The EBMT was also invited to participate in two other meetings contributing to related guidelines and standards on human tissues and cells.

1. Stakeholders Conference on a future European Regulatory framework for human tissue-engineered products, Brussels, 16 April 2004 (Attended by Dr Ineke Slaper Cortenbach (JACIE) and Dr Francesco Frassoni (EBMT)

2. Meeting of the Council of Europe Group for Specialists on Quality Assurance for Organs, Tissues and Cells, Strasbourg, 15 March 2004 (represented on the Committee of Experts by Dr Diana Samson, JACIE Medical Consultant.

The first meeting resulted in a framework proposal for Tissue Engineered products, which went out for Open Consultation in June 2005. JACIE and the EBMT continue to input into developments of the regulatory framework in this area.

The Council of Europe meeting produced a draft 3rd Edition of the Guide to safety and quality assurance of organs, tissues and cells. While these are non-binding guidelines, it is strongly felt that they form a sound basis for good practice in transplantation. JACIE was invited to contribute to the drafting of the Guide. In addition, contributions from the Council of Europe were incorporated into the technical annexes of the EU Directive. JACIE will provide feedback on this by the consultation deadline of 30 November 2005.

Due to the fact that the technical requirements to the Directive are still under development it was not possible to sign off on the JACIE Standards against the Directive prior to production of the Second edition of the JACIE Manual. However, it is clear that the JACIE Standards, whilst more rigorous than the EU Directive, will be fully in line with the standards set by the European Union.

A 3rd edition of the JACIE/FACT Standards is currently under development. Over the course of 2005 the Standards have undergone a detailed review process and it is anticipated that the 3rd edition of the Standards will be available for public consultation before the end of 2005. The standards are being developed once again in collaboration with JACIE's North American counterpart the Foundation for Accreditation of Cellular Therapy (FACT), making them International, as opposed to solely European standards. The JACIE representatives on the Committee have worked to ensure that issues relevant to the European context are fully reflected in the Standards and to guarantee that developments to the Standards are in-line with the EU Directive and the final technical annexes.

Contribution to stated objectives:

Through its activities in this area JACIE has contributed to the development and of standards in the field of human tissues and cells and facilitated input from the scientific community into the EU Directive. It has also promoted knowledge and understanding of the role of standards and accreditation in this area of key concern for the EU. The fact that the JACIE programme will be able to fulfil the

requirements of the EU Directive contributes to encouraging harmonisation across Europe and the International nature of the JACIE Standards contributes to the overall harmonisation process of standards for human tissues and cells.

Deliverable 2	**Development of guidelines in specific areas**
Work packages	**2.1** Production of 2nd edition of the JACIE Accreditation Manual incorporating the 2nd edition of the Standards. **2.2** Distribution of 1500 copies to healthcare professionals, health authorities, EC, etc.

Similarly to the deliverables under Work Package 1, the production and distribution of a 2nd edition of the JACIE Accreditation Manual were important programme activities corresponding to the following project objectives:

- *harmonization of JACIE standards and programme of accreditation with EU Tissue and Cells Directive*
- *promotion of the JACIE accreditation programme amongst healthcare professionals and national authorities with a view to harmonization across the Community*

Over the course of 2004 JACIE worked in collaboration with its American counterpart FACT to produce a second edition of the FACT/JACIE Manual. The final approved version of this manual was received from FACT in November 2004. The manual was closely reviewed by the JACIE Executive Committee, inspectors and members of the JACIE Board to ensure that it was in accordance with the 2nd edition of the JACIE Standards and European requirements. The JACIE office worked throughout December and January to adapt the manual to JACIE and European terminology and requirements. Design work and printing took place in February and 1500 copies of the manual were produced as planned. The JACIE Manuals were attractively designed to create a brand image for JACIE and to make them practical for use within a hospital setting. Ring-binders were used to allow for easy photocopying and so that the three key sections of the manual: clinical, processing and laboratory could be easily separated for use.

The manual was distributed to healthcare professionals and health authorities in the following ways:

- 1002 copies were mailed to EBMT member centres (2 per centre) at beginning of March 2005
- 131 copies were mailed to JACIE inspectors
- 18 copies were distributed to EBMT Board members at the EBMT annual congress in Prague, March 2005*
- 40 copies were distributed to JACIE Board members at the EBMT annual congress in Prague, March 2005 for personal use and to share with national authorities. Extra copies were also sent directly to national authority contacts listed*
- 17 copies were distributed at a meeting with representatives of National Societies and registries at the EBMT annual congress in Prague, March 2005
- 17 copies were distributed at a meeting with representatives of Donor registries at the EBMT annual congress in Prague, March 2005

- 10 copies were sent to key organisations working in the field: Council of Europe, World Marrow Donor Association, NETCORD, EUROCORD and FACT
- 24 were distributed at a JACIE Inspector training course held in Athens in September 2005*
- The remaining copies are retained in the JACIE Office for distribution in response to requests for information and for use in future training course, including a Quality Management Course organised in Greece on November 2005.

A copy of the JACIE Manual and lists* of the various recipients indicated above are included in the appendices and supporting document submitted with this report (WP 2.1 Production of Second edition of JACIE Manual).

The JACIE manual is publicly available for download from the JACIE website: **www.jacie.org**

Contribution to stated objectives:

The incorporation of the 2nd edition of the JACIE Standards into the JACIE Manual ensures that the JACIE accreditation programme is in line with the EU Directive on human tissues and cells. By so doing JACIE is able to play an integral role in standard setting, inspection and accreditation of healthcare facilities involved in haematopoietic stem cell collection, processing and transplantation and contributes to harmonisation of systems in Europe.

The distribution of the manual to all EBMT centres signifies that 83%* of active transplant centres in Europe have received copies of the JACIE manual. This is important not only for raising awareness of and promoting the JACIE programme of accreditation amongst healthcare professionals, with a view to adoption of the JACIE standards across Europe. It also contributes to a more general awareness and culture of quality management and standards in the area of collection processing and transplant of haematopoietic stem cells.

The foreseen programme and related objectives are felt to have been adequately fulfilled in this area.

* Based on results of 2003 EBMT Activity Survey, there are 602 BMT centres in Europe

Deliverable 3	**Production of educational materials**
Work packages	**3.1** Production and distribution of 300 JACIE information packs **3.2** Delivery of a JACIE educational session as part of the ESH-EBMT Postgraduate Training Course in Budapest (May 2004) **3.3** Model materials (SOPs and Quality management Plans, etc.) for sharing of best practice made available for download from JACIE web site

The production of educational and other informative materials as elaborated in the proposal document were aimed at the promotion of JACIE, as well as to raise understanding of quality management and assist transplant facilities in the implementation of the JACIE Standards.

Another important objective was to facilitate the exchange of best practice between healthcare professionals in Europe.

The following activities in this area were carried out over the course of the project:

1. JACIE Information Packs

300 information packs were produced and distributed to health authorities throughout Europe and to healthcare professionals/authorities in Applicant Countries and Member States in the process of being brought into the network of JACIE National Representatives.

The JACIE Information Packs contained a number of key documents:

- **A covering letter** outlining the contents of the pack and highlighting the implications of EU Directive 2004/23/EC
- **JACIE Information Leaflet**
- **Second edition of the JACIE Standards**
- **EU Directive 2004/23/EC** on setting standards of quality and safety for the procurement, testing, processing, preservation, storage and distribution of human tissues and cells

The JACIE Information Packs were attractively designed to create a brand image for JACIE and to promote interest in the contents.

The Information packs were distributed in the following ways:

- 88 copies were mailed to EBMT member centres with the JACIE Manual at beginning of March 2005
- 19 copies were distributed to EBMT Board members at the EBMT annual congress in Prague, March 2005*

- 40 copies were distributed to JACIE Board members (including JACIE National Representatives) at the EBMT annual congress in Prague, March 2005 to share with national authorities. See also list of national authority officials*
- 60 copies were distributed to national representatives of countries in the process of joining the network of JACIE National Representatives* at a JACIE Outreach meeting organised at the EBMT annual congress in Prague
- 17 copies were distributed at a meeting with representatives of National Societies and registries at the EBMT annual congress in Prague, March 2005
- 17 copies were distributed at a meeting with representatives of Donor registries at the EBMT annual congress in Prague, March 2005
- 51copies were subsequently sent out by the JACIE Office in response to requests for information received via the JACIE Online system

A copy of the JACIE Information Pack and lists* of the various recipients indicated above are included in the appendices and supporting document submitted with this report (WP 3.1: Production and distribution of JACIE Information Packs).

The contents of the JACIE Information Pack, including EU Directive 2004/23/EC are publicly available for download from the JACIE website: **www.jacie.org**

2. JACIE educational session, ESH-EBMT Postgraduate Training Course, Budapest (May 2004)

A meet the expert session entitled "JACIE: accreditation of a transplant centre" was held as part of the Eighth ESH-EBMT Training Course in Budapest on 8 May 2004. The only budgetary provision for this course was for the printing of materials. The opportunity was taken to print the 2nd edition of the JACIE Standards for distribution to all participants) for reference throughout the training course. A copy of the Standards document and list of participants (120 delegates) is included in the appendices and supporting documentation submitted with this report ((WP 3.2: JACIE Education Session, Budapest, May 2004).

3. Production of model materials

The JACIE Office worked with Kerteza trainers at the end of 2004 and beginning of 2005 to compile a set of model quality management materials to share with healthcare professionals starting out on or in the course of preparing their transplant programme for JACIE accreditation. A copy of the materials is included in the supporting documentation submitted with this report (WP 3.3 Model materials for sharing of best practice). The contents are as follows:

1. Quality Management Plan framework
2. Sample Quality Management Plans for:
    (a) Clinical units
    (b) Collection facilities
    (c) Processing facilities

(d) FACT (USA) Collection & Processing

3. SOPs for writing SOPs
4. SOP for document control
5. Appendices:
   (a) List of suggested SOPs
   (b) Sample plans for implementing QMPs taken from group sessions at JACIE centre (QM) preparation training courses held in January 2004

The Quality Management Plan framework (Quality Manual) was produced by Kerteza, based on the Dutch CCKL manual and with close reference to the Second edition of the JACIE Standards. The other materials were put together based on real documentation submitted by centres inspected in 2004. All quality documentation submitted in English was reviewed by the JACIE Office and Patrick Corstiaans of Kerteza training to identify the best materials, which were adapted and improved where necessary, prior to being made anonymous. The materials were reviewed by the JACIE Medical Consultant to approve content based on her experience of 24 inspections over the course of 2004.

Contribution to stated objectives

An important objective in producing the Information Packs was to raise awareness and understanding of the JACIE programme and draw attention to the EU Directive and its implications for collection and processing facilities. The Information Packs were initially intended for Programme Directors and health authority officials in countries in the process of being brought into the network of JACIE National Representatives. During the course of the project JACIE National Representatives from the countries forming part of the JACIE network identified that informative materials on JACIE and the EU Directive would help them promote JACIE in their discussions with health authority officials. For this reason JACIE Information Packs were distributed to all JACIE National Representatives, not only those outside the JACIE Network. The National Representatives went onto meet with health authority officials in their countries and shared these materials with them, thereby raising the profile of JACIE across Member States.

Very early on in the project the importance of model materials for sharing of best practice became evident. At the JACIE training courses organised in January and May participants asked for materials produced during the course to be made available for download from the EBMT website to help them in preparing their facilities for JACIE accreditation. These materials were made available at the time, but it was not until after a substantial number of inspections had been performed that the best materials could be identified and compiled into a consolidated document. This document is of great value to facilities which are considering or in the process of applying for JACIE accreditation and do literally not know where to start. The documents give them a sample of how other facilities have approached JACIE accreditation and provide a good base to work from, although it is made clear that the materials are not intended to be prescriptive and that each facility must adapt the materials and produce a quality management plan that meets their own requirements.

B. Implementation of JACIE accreditation programme

Deliverable 4	**Establishment of a functioning European JACIE Office**
Work packages	**4.1** Establishment of a European JACIE Office

Another main aim of the "JACIE" project was to provide vital impetus to the JACIE programme through the implementation of the JACIE accreditation programme in a core number of centres in Europe. In order to facilitate this process it was necessary to put in place effective centralised administration, through the creation of a European JACIE Office.

Taking advantage of the infrastructure and resources that were available at the EBMT Secretariat Office, the JACIE Office was established in December 2003, alongside the EBMT Secretariat in Hospital Clinic, Barcelona.

Eoin McGrath, formerly the Administrative Assistant to the EBMT Secretariat, was promoted to JACIE Project Officer and throughout 2004 and 2005 has dedicated 2/3rd of his time to the JACIE Office. An Administrative Assistant (Sara Notley) and Medical Consultant (Dr Diana Samson) were recruited and trained at the beginning of 2004. Throughout 2004 Sara Notley worked part-time for the JACIE Office and part-time for the EBMT Secretariat. Fiona Mc Donald, the EBMT Executive Officer, provided project management support throughout the project.

Administrative procedures were developed and streamlined (application forms, document checklist, inspection checklist, format for inspector and consultant report, etc.) by the Project Officer throughout 2004 and the majority of these systems have been incorporated into the JACIE Online system (reference deliverable 5). All of the JACIE project activities from 1 January 2004 to 28 February 2005, as well as all of the project reporting were coordinated by the JACIE Office.

A Medical Consultant, Dr. Diana Samson, was contracted through Imperial Consultants at the beginning of January 2004 to work one day per week on the JACIE project throughout 2004. Dr. Samson attended the JACIE Quality Management course held in Barcelona from 23- 24 January 2004 for training purposes. She also participated in a JACIE Inspector training course in the UK, organised by the British Society for Blood and Marrow Transplantation (BSBMT) in collaboration with JACIE in September 2004. Over the course of 2004 Dr Samson participated as an observer on two JACIE inspections in the UK (Bristol and Oxford) to increase her knowledge and understanding of the inspection process. Dr. Samson works remotely from London and throughout 2004 provided the following professional services to JACIE:

1. Liaison with JACIE Office (including periodic visits to the Barcelona office)
2. Review of JACIE applications, checklists & supporting documents submitted prior to inspection

3. Review of inspection reports; follow-up over report findings and production of a summary recommendation report to the JACIE Board
4. Participation in JACIE Board meetings
5. Production and publication of reports and publications
6. General consultancy over standards, the JACIE accreditation process and ongoing development of the JACIE programme

Dr. Samson was promoted to JACIE Medical Director by the JACIE Board on 7 October 2004 and as of January 2005 has worked 2 days per week for the JACIE Office.

A full JACIE Board was appointed in March 2004 and two full Board meetings were held in 2004:

- JACIE Board meeting, Barcelona, 28 March 2004
- JACIE Board meeting, Amsterdam, 7 October 2004

Minutes of the Board meetings and slides presented at those meetings are included as supporting documents in the appendices to this report (WP 4.1: Functioning JACIE Office).

An Executive Committee was appointed to deal with the day to day management of the JACIE programme and to act as the steering committee for the "JACIE" project. Meetings and conference calls of the Executive Committee have been held every month (as opposed to every 2 months as originally planned) in this critical period of consolidation of the JACIE programme.

An overview of the Board appointed in March 2004 is presented below.

Executive Committee
President: Alvaro Urbano Ispizua, Barcelona (EBMT)
Vice-President: Ineke Slaper-Cortenbach, Utrecht (ISCT)
Medical Director: Diana Samson, London
Co-opted member: Derwood Pamphilon, Bristol, UK

National Representatives:

Hildegard Greinix, Austria
Marc Boogaerts, Belgium
Vladimir Koza, Czech Republic
Niels Jacobsen, Denmark
Tapani Ruutu, Finland
Mauricette Michallet, France
Norbert Schmitz, Germany
Damianos Sotiropulos, Greece
Alessandro Rambaldi, Italy
Brigit Bar, The Netherlands
Gunnar Kvalheim, Norway
Jerzy Holowiecki, Poland
Mikulas Hrubisko, Slovakia
Carlos Solano, Spain
Per Ljungman, Sweden
Alois Gratwohl, Switzerland
Osman Ilhan, Turkey
Derwood Pamphilon, United Kingdom

Sectoral Representatives:

Peter Wernet, NETCORD
Barry Quinn, Nursing
Jackie Cornish, Paediatrics

An EBMT Annual Report, detailing the achievements of the JACIE project was produced at the end of March 2005 and is included as part of the supporting documentation submitted with this report (WP 4.1: Functioning JACIE Office).

JACIE stationery was designed and printed as part of the project and has proved important in creating a brand image for JACIE:

- Headed paper (1000 copies)
- Envelopes (1000 letter size; 1000 A4 size)
- Business cards: Dr Diana Samson (200), Dr Ineke Slaper-Cortenbach (200), General office (200)

Contribution to stated objectives

The establishment of a JACIE Office and corresponding strengthening of central resources has proved fundamental to the effective management of the JACIE programme and the implementation of the "JACIE" project. The JACIE Office is now firmly established in Barcelona. The promotion of Eoin Mc Grath to JACIE Executive Officer and the recruitment of a new full-time Administrative Assistant to the JACIE Office in May 2005 are testimony to the success of the office. The EBMT has continued to support the JACIE Office in 2005 with a grant of 57,000€. An inspection fee (4000€ in 2005) has also been introduced to support the core costs of the office and the cost of inspections in 2005.

Deliverable 5	**Mechanisms for collecting data and information**
Work packages	**5.1** Development of an effective IT system (JACIE Online) for administration & management of the JACIE programme. The system will facilitate collection, tracking and monitoring of information on implementation of JACIE accreditation **5.2** Download & upload of JACIE documentation via the JACIE system

Development of an effective IT system for the management of the JACIE programme was central to the project and has been one of our major successes.

The delivery of the system was core to a number of key objectives:

- *Strengthening central resources for managing and administering the JACIE programme and enhancing effectiveness of the existing JACIE network*
- *To contribute to the comparability of data across Member States*

Centralisation of the JACIE programme in the Barcelona office was regarded by JACIE National Representatives on the whole to be a positive step forward in the implementation of JACIE, so as to avoid duplication of efforts and ensure that costs be kept to a minimum. Concerns were however expressed that the process should not become over-bureaucratic and that access to data and information on progress of implementation of JACIE at the national level should be readily available to the National Representatives to share with national and local authorities.

With these factors in mind the development of an IT system that would manage the accreditation process from initial application, through document submission, inspection, reporting and final accreditation was envisaged. The objective was that the system would hold data on each of the key stages of the process enabling reports to be generated on the progress of accreditation at the centre, national and European level.

Download and upload of documentation via the online system were regarded as essential components of the system and fundamental to the future success and sustainability of the JACIE programme, in terms of keeping paperwork and costs to a minimum. Accreditation involves the generation of a large quantity of documentation, which must be reviewed by the inspectors in advance of the inspection and copies maintained by the JACIE Office to demonstrate the validity of the accreditation. To copy these documents and mail them to inspectors, even in electronic format, would create a considerable amount of work, add delay to the process and increase costs significantly.

Activities

The IT Company (Polymita Technologies) subcontracted to develop the online system was selected at the end of 2003, following a tender process in line with Commission requirements. Documentation related to the tender process was submitted with the original proposal and are included in electronic format in the CD ROM accompanying this report (Ref: Management Documents Submitted/IT Tender Process. The company was ready to start work at the beginning of January 2004. Due to a delay by the Commission in preparing the contract documentation it was not possible to begin work on the system until April 2004 and this impacted on the planned delivery schedule.

Polymita Technologies worked on system development from April to October. The JACIE Project Officer represented the client throughout the development stage and was supported in negotiations with Polymita by the JACIE Project Manager. Regular meetings were held between Polymita and the JACIE Office and copies of the agendas and minutes of these meetings, as well as the system specification, schedule and detailed breakdown of resources employed, are included as supporting documents in the appendices to this report (WP 5.1 JACIE Online system).

System development was completed in October and user-testing took place throughout November. The JACIE Project Officer and Administrative Assistant carried out the user testing and reported bugs to Polymita for fixing. Sign off on full delivery of the system took place on 15th December 2004. The system has been available for consultation online since that date at **www.jacie.org**

The amount of time spent by Polymita Technologies on delivering the system was much higher than originally anticipated and the final system delivered is much more robust and flexible than set-out in the original programme specification. Polymita Technologies however respected the fixed cost contract

agreed and completed delivery to the client's satisfaction for the price agreed in the original tender document.

The JACIE Online system is working effectively. Its function and main features are described below and a number of screen shots have been included to demonstrate elements of the system. The public section of JACIE Online can be consulted freely online. Information on individual centres is only accessible by the centre, JACIE administrator, inspector and Medical Consultant, as intended. Reports on implementation of accreditation can however be extracted from the system as detailed under deliverable 6 below.

System description and overview

JACIE Online

is an internet-based management tool to assist applicant centres and JACIE administration to handle requests for accreditation. It automates many procedures and keeps all participants up-to-date on the progress of applications.

Features:

Applicant centres

- Make the initial application online
- submit the required supporting documentation electronically
- see feedback from the JACIE administrator, medical director and inspection team
- monitor their progress throughout the process

Medical Director

- At-a-glance view of work programme
- Ready access to all documentation required
- Comments facility

Inspectors

- See upcoming schedule of inspection visits on online calendar
- Maintain inspection history
- Access to all comments and documents submitted by relevant centre
- Update contact details and profiles
- Report on inspection online and exchange comments via online discussion

National Representatives

- On-demand overview of progress of JACIE in respective country
- Breakdown of centres by position in the accreditation process
- Ability to export reports for presentations to national health authorities, hospital management etc.
- Facility to take part in Board decision on a centre's accreditation award.

JACIE Administration

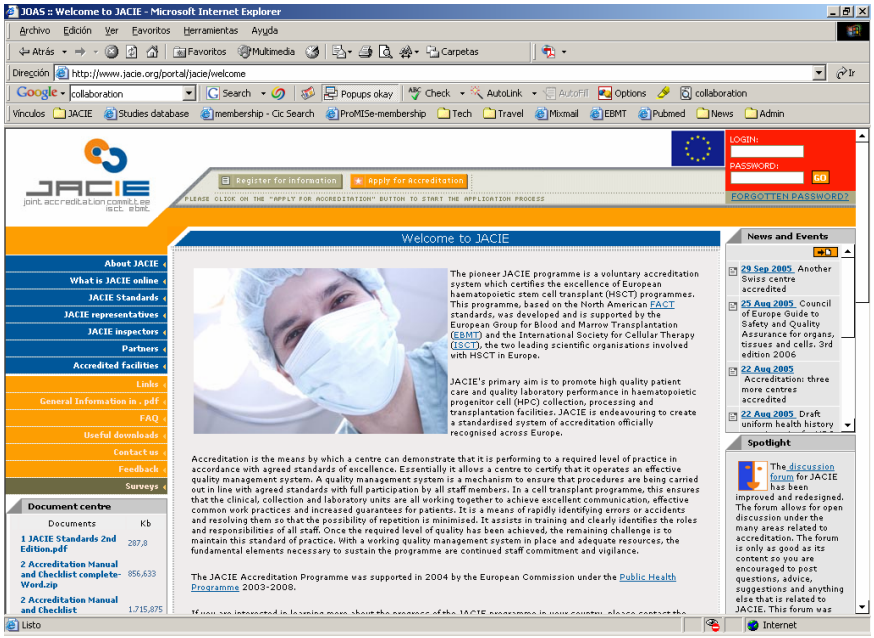
- Keep abreast of all applications
- At-a-glance overview of all centres in the process

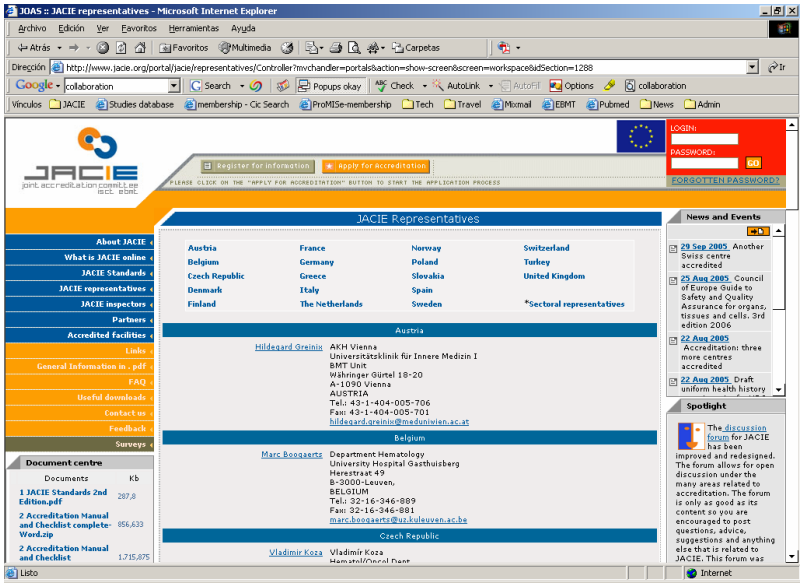
- Comment on documents
- Maintain all contact details in central location
- Distribute documents and information to inspection teams, Board members and medical director
- Overall management of access for all users

Screenshots of public site and views of application information including:

- Application form
- Document submission
- Inspection report
- Medical Director's report

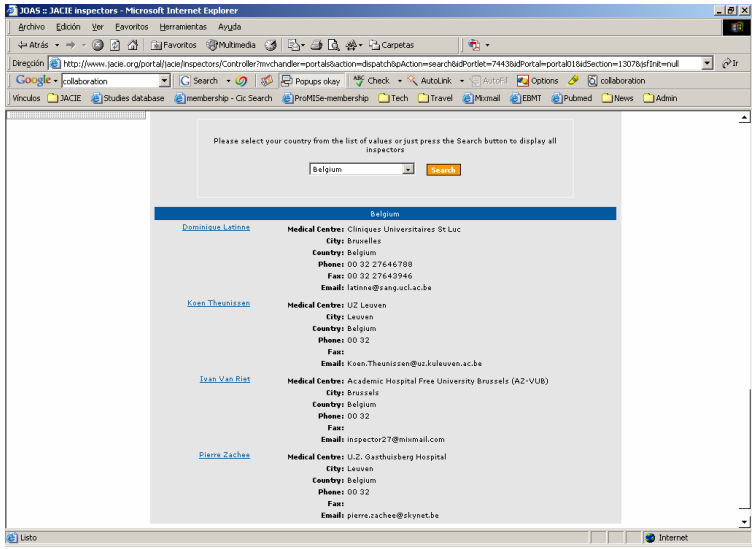
JACIE Home Page: The web site provides general information on the JACIE Accreditation Programme, lists JACIE National Representatives, JACIE Inspectors, Accredited Centres



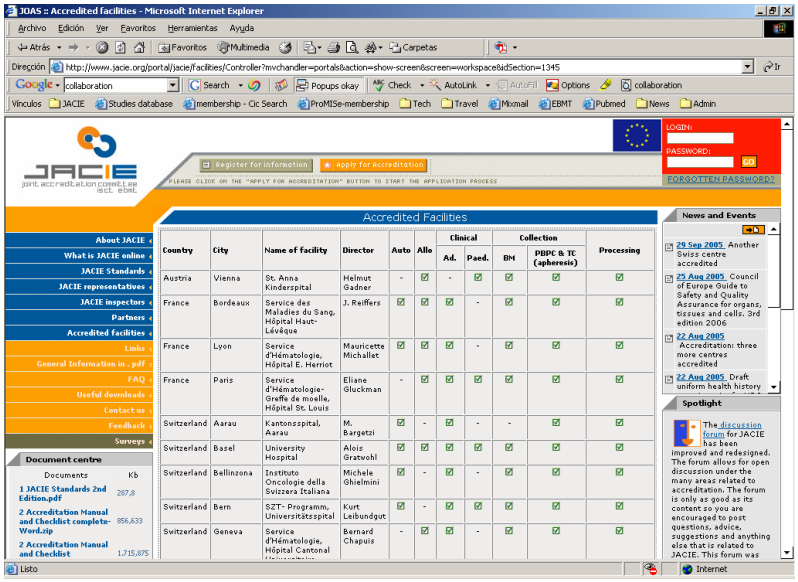


Listing of JACIE National and Sectoral Representatives

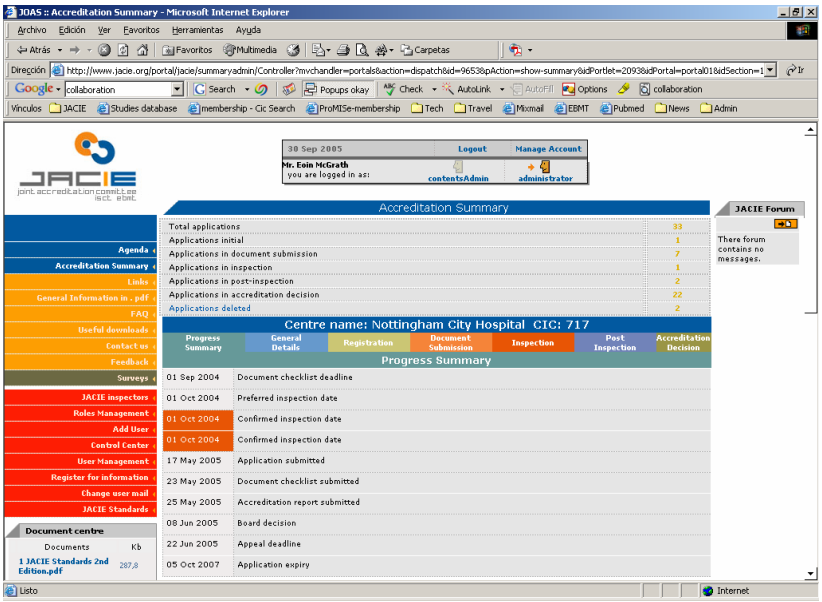
Listing of inspectors by country



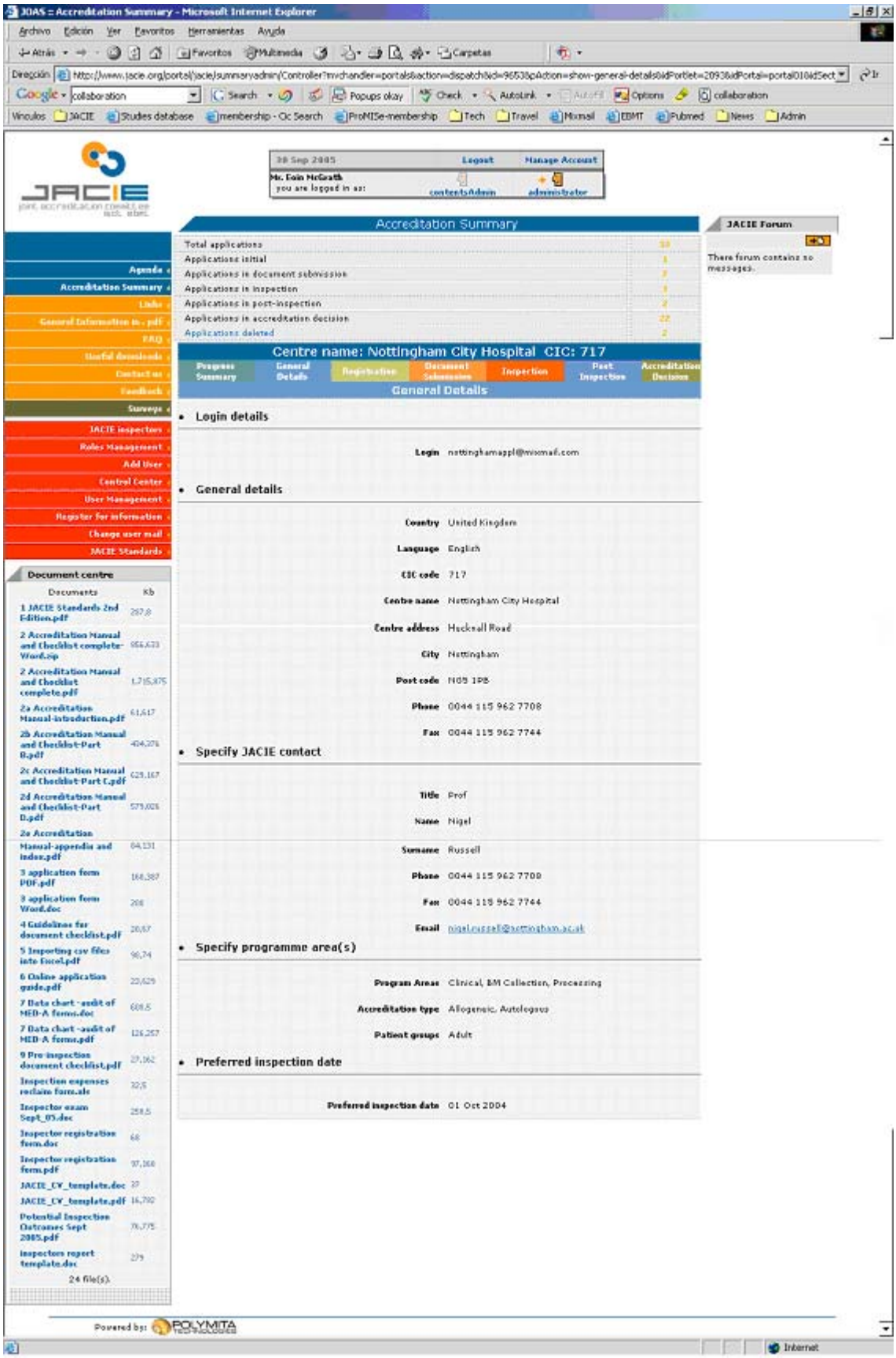
Accredited centres



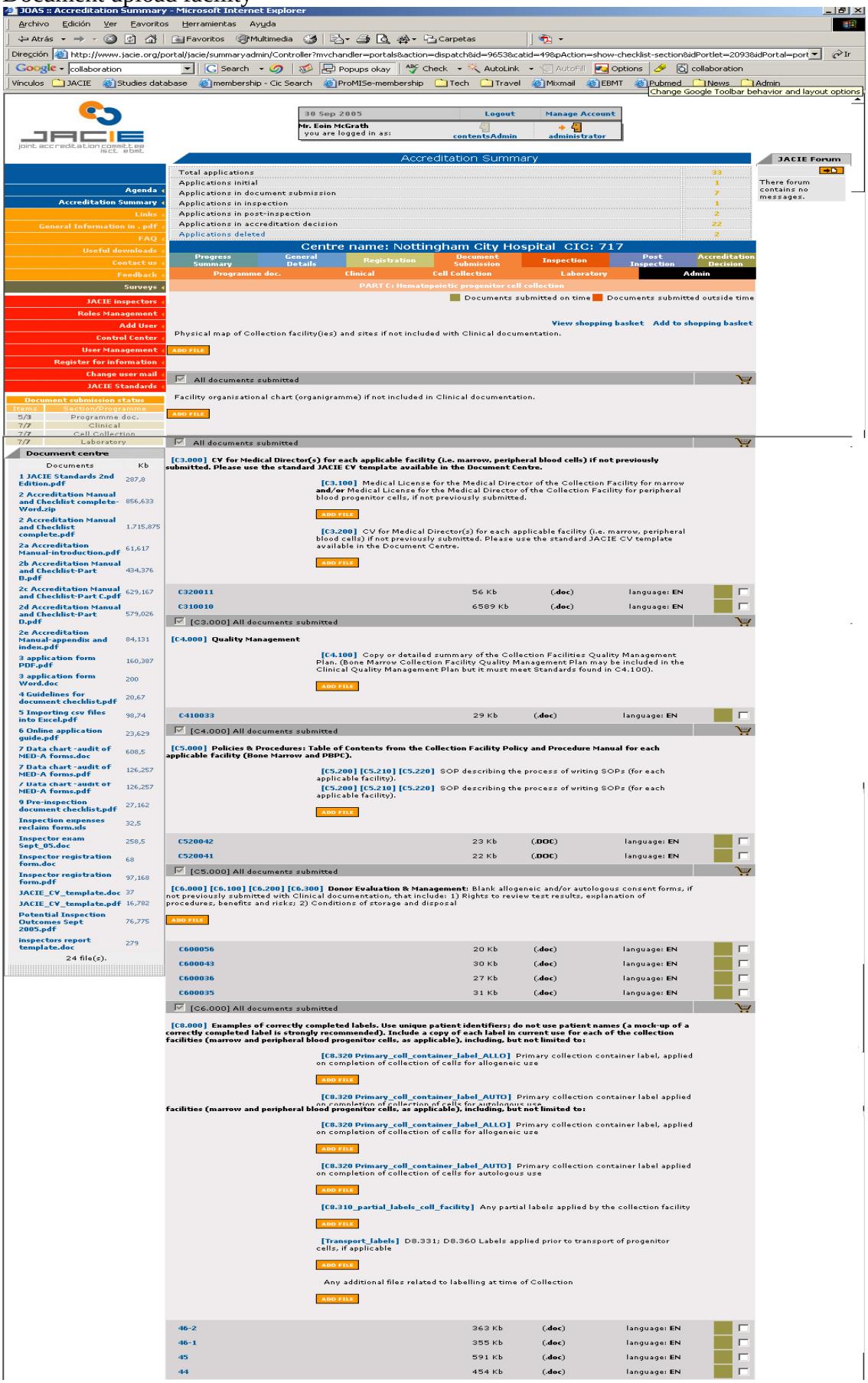
View of calendar of key dates in an application lifetime. Available to applicant, inspectors, JACIE administrator, JACIE Medical Director, JACIE National Representative



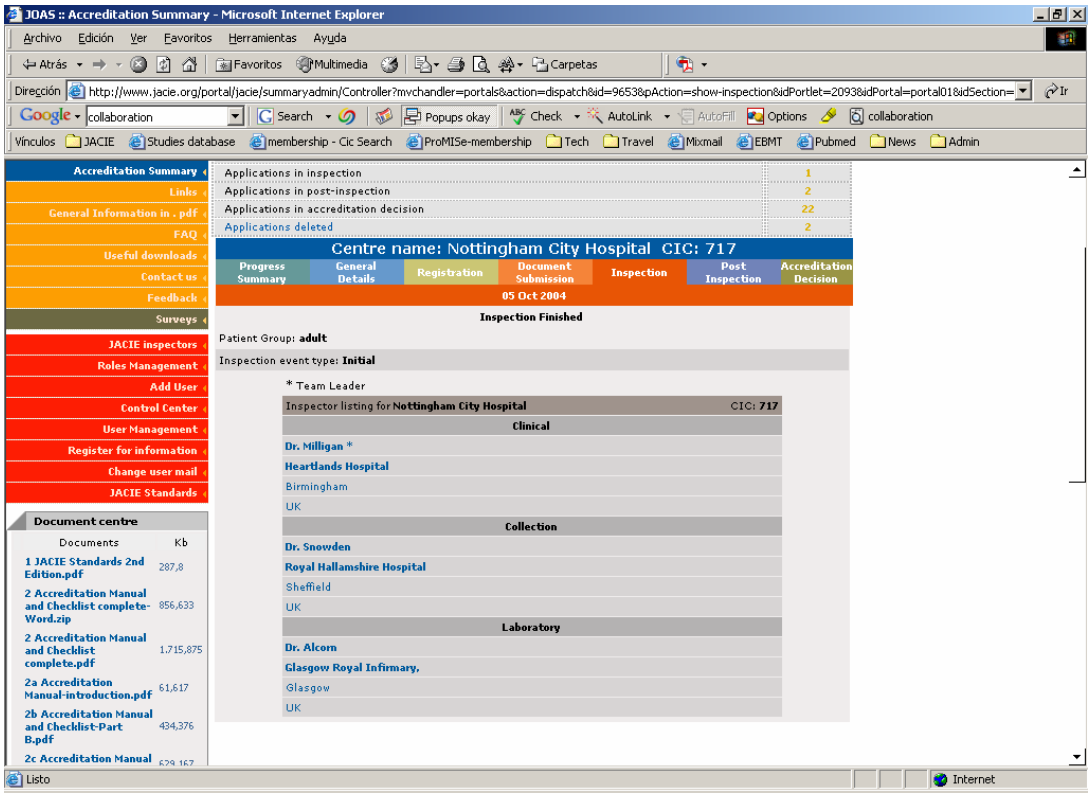
Completed application form showing general details and area of accreditation being applied for



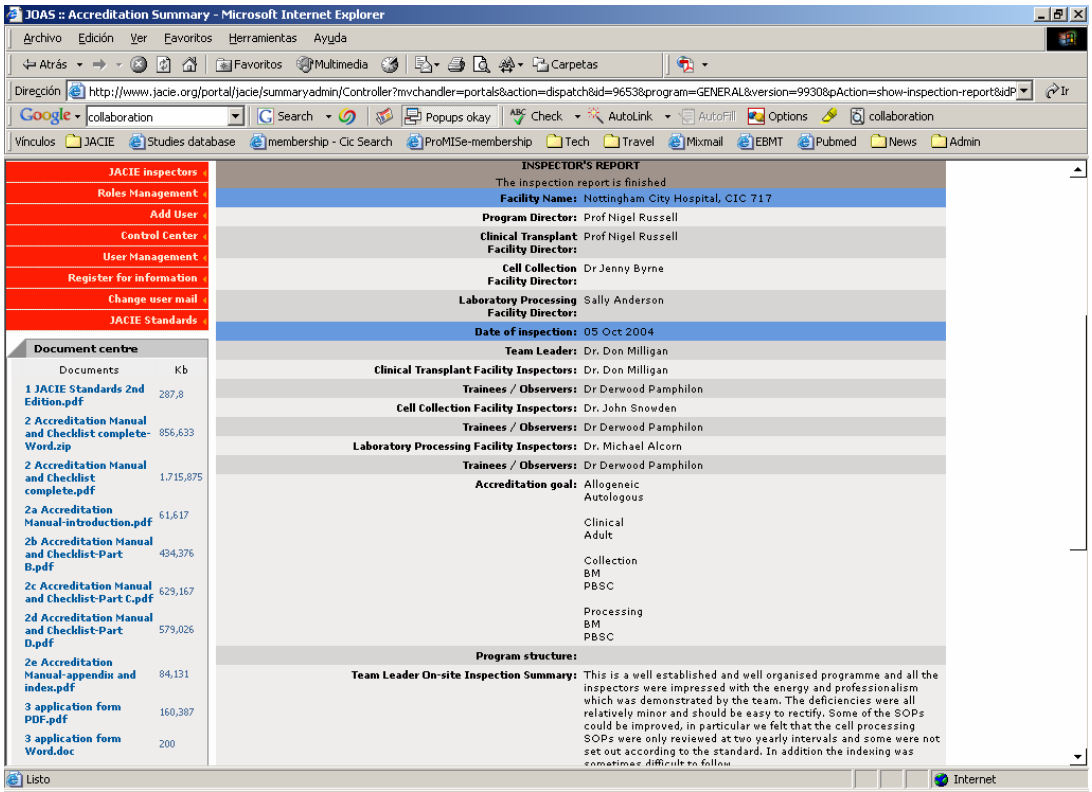
Document upload facility



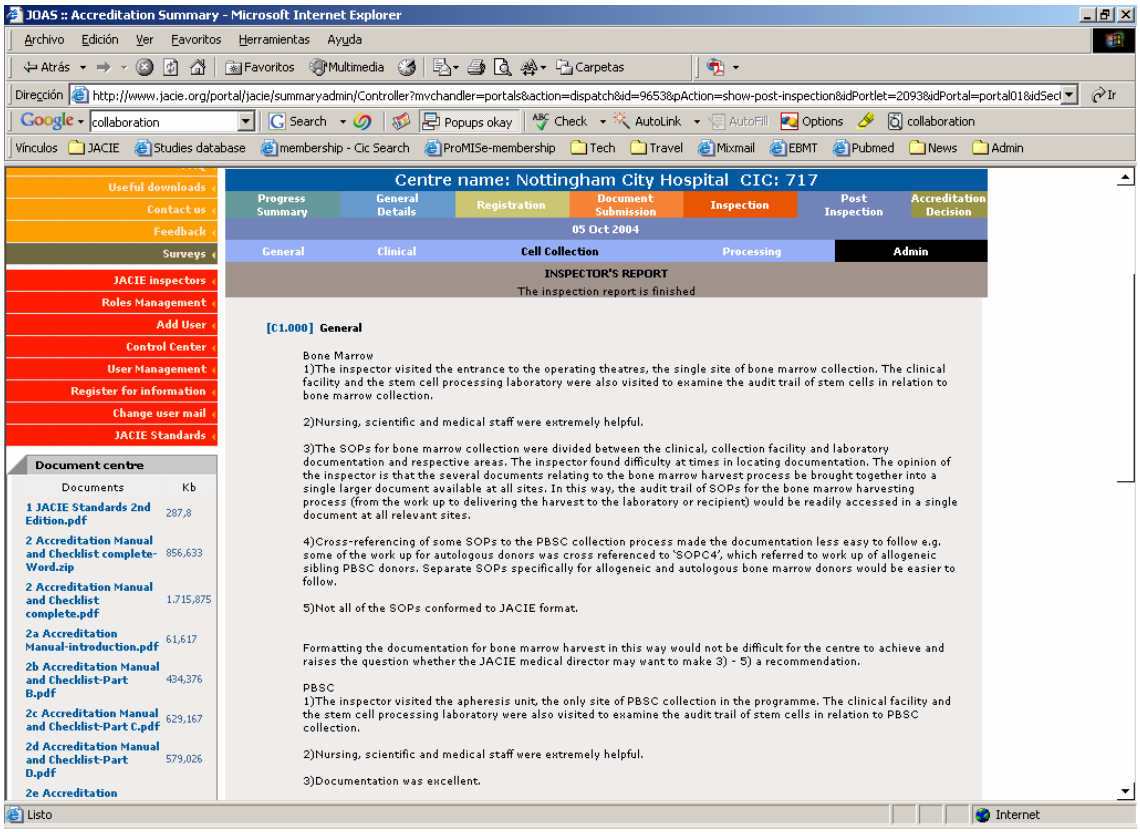
Inspection details



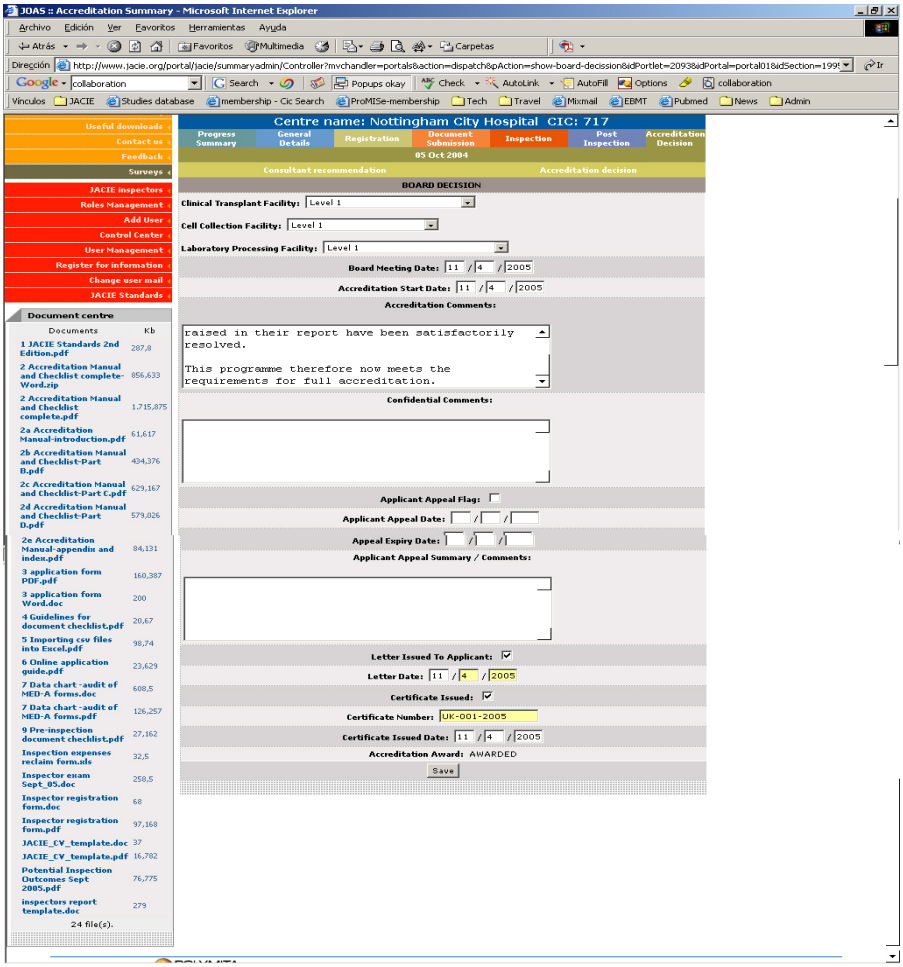
Inspection Report online (1)



Inspection Report online (2)



Medical Director's report online with recommendation for Accreditation



As the system was not completed until the end of 2004 it was not possible for the centres who participated in the "JACIE" project to use the system to process their applications. For this reason centres were not involved in the user testing of the system. This was conducted by the Project Officer, the Administrative Assistant and the JACIE Medical Consultant who tested the functionality of the various roles (centre, inspector, national representative, Medical Consultant and system administrator) and completed bug reports. A compilation of the bugs reported and fixed prior to sign off is included as supporting documentation in WP 5.1.

All of the legacy data from the 25 inspections conducted in 2004/early 2005 has now been entered on the system. All new applications in 2005 (16) have been submitted by applicant centres via the online system. The system is fully functioning, including document upload (by centres) and download (by inspectors/JACIE Office) and all reporting (Inspector reports and Medical Consultant reports) are submitted online and stored within the system.

A **User Guide to JACIE Online** has been produced by the JACIE Office and is issued to all new users of the system, according to their role. The guide details the steps for accessing the system for the following users:

For the Applicant

- Online application
- Online Document submission

For the Inspector

- Inspector Login and Document Download
- Online Inspectors Report Guidelines

For the Medical Consultant

- Online Medical consultant Report Guidelines

For the Administrator

- Online login for the administrator
- Online assigning of Inspectors
- Online Inspectors report administration
- Online accreditation administration

A copy of the guidelines is included as supporting documentation under WP 5.1 in the appendices accompanying this report.

Throughout 2004 the inspection documentation was submitted by centres and circulated to inspectors in CD ROM format. The cost of sending these documents, together with a hard copy of the inspection list via courier cost the JACIE Office approx 30€ per inspector (average 3 inspectors/inspection @ 25

inspections = 1875€). This was a considerable improvement on the first 2 inspections where boxes of documents weighing around 13 kilos were delivered to the office. This clearly illustrates the lack of feasibility of a paper system.

All of the documents from the 2004 inspections were loaded onto the system in 2005 (over 2500 documents). This proved a time-consuming process for the JACIE Office because each of the documents had to be correctly labelled for upload onto the system. For all new inspections documents are uploaded by the centres themselves. The system demands discipline in the naming of documents and ensures that the documents are uploaded onto the system in a structured way with generic labels, thereby representing a large saving in time for the JACIE office and applicant centres.

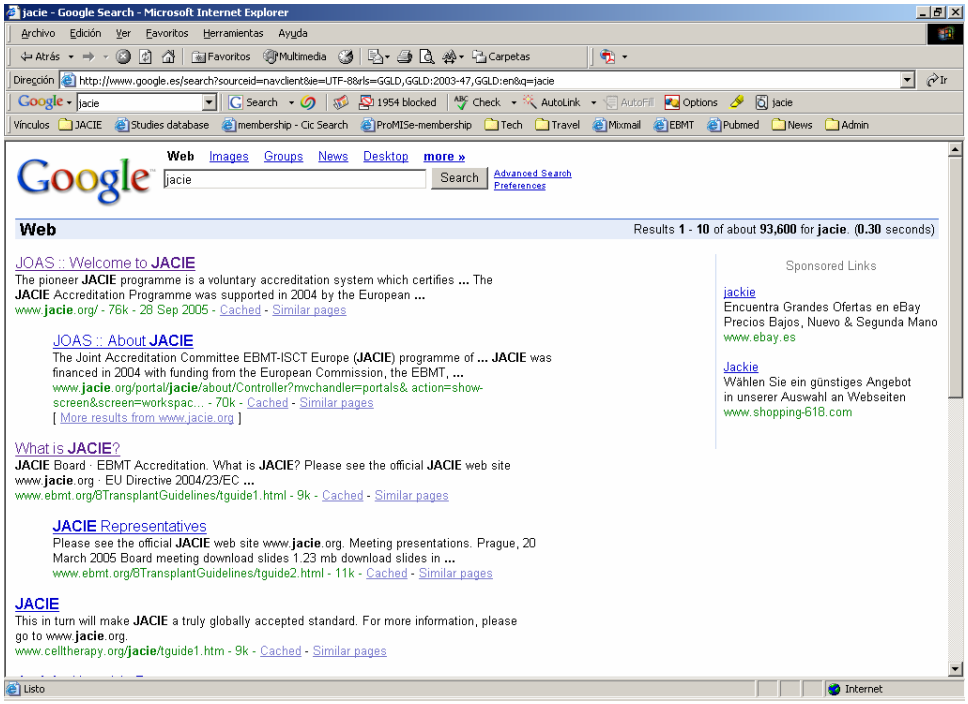
Contribution to stated objectives

Although the system was delivered later than scheduled and could not be fully applied during the course of the project, the fact that all of the legacy data for 25 inspections has been entered on the system and the system is now being used on a daily basis to manage the accreditation process from initial application to final sign-off on accreditation illustrates that the stated objectives were met.

As all of the data from the 25 inspections is now in the system, it is possible to access the centre files or extract reports from the system with data on all aspects related to the accreditation of each centre.

JACIE's North American counterpart FACT employs a largely paper-based system for administering the FACT accreditation programme. They are currently looking at the JACIE system and considering the possibility of adapting it to their needs.

A search for JACIE on www.google.com returns the official JACIE site as the first, second and third result. Result is from 30/09/2005.



Deliverable 6	**Mechanisms for disseminating data and information**
Work packages	**6.1** Generation of progress reports via the online system **6.2** Establishment of an online forum where centres, inspectors, etc can exchange experiences and share best practice **6.3** Monthly JACIE e-bulletins to JACIE National Representatives

The mechanisms for disseminating data and information under Work Package 6 were directed in part at the following objectives:

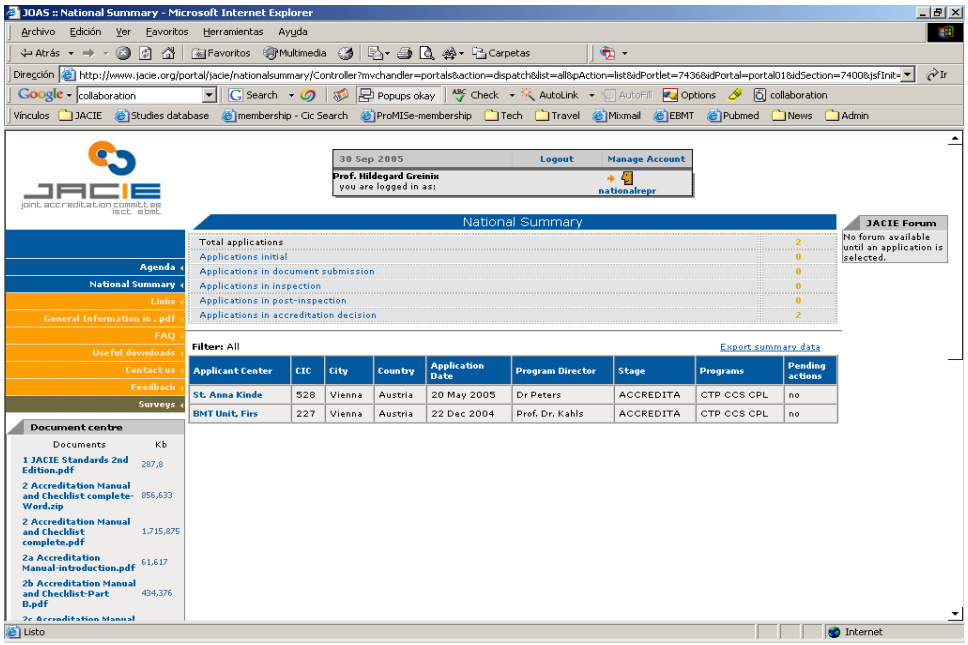
- *To promote the programme amongst medical professionals, health authorities, etc. with a view to encouraging harmonisation of standards and systems across the EU*
- *To strengthen central resources for managing JACIE and enhance the effectiveness of the JACIE network*
- *To facilitate the sharing of best practice*

The following activities were carried out under the different work package deliverables:

6.1 Progress reports

The JACIE Office can use the JACIE Online system to export key information on all applications to an Excel spreadsheet. This report indicates the current stage of any given application (see the Application Status Report spreadsheet included as supporting documentation under WP 6.1 and allows the JACIE Office to produce national overviews for the JACIE National Representatives to share with health authorities, etc. This data will enable National Representatives and authorities to monitor the status and rate of JACIE inspection in their own country and use this data for planning and management purposes.

JACIE National Representatives can also login to the system at any time and view the state of applications from their own country. See example in screenshot for Austrian representative below.



Overviews of all accredited facilities, qualified inspectors (searchable by country) and list of JACIE National Representatives can also be easily accessed online.

It is also possible to extract the information contained in the inspection reports and consultant reports into a word document to allow analyses related to the accreditation programme (e.g. common deficiencies) A sample extract report on common deficiencies is included as supporting documentation under WP 10.2.

6.2 Online forum

The online forum was created in January 2005. The forum is hosted on the server of EBMT's main partner in JACIE, the International Society for Cellular Therapy **www.isct.org**, based in Vancouver, Canada. The forum is accessible via the homepage of JACIE Online and is administered and monitored by the JACIE Project Officer. Following an initial basic design in early 2005, a more sophisticated version was launched in August 2005. Content from the original forum has been included in the new version. In order to access the forum, the user must register. The user can post under a variety of topics, search the contents, reply to questions posted by other users, bookmark topics so that they are alerted when a new post is added to the topic and contact other forum members directly. Screenshots of the forum, including a list of topics and forum members, as well as sample discussions are included as supporting documentation in the appendices to this report (WP 6.2 Online JACIE forum).

6.3 Monthly JACIE e-bulletins

Due to time resource constraints in the JACIE Office these bulletins were unfortunately not produced. It was felt that the regular updates in the March, July and November editions of EBMT News, as well as the detailed reports given at the JACIE Board meetings in March and in early October, provided National Representatives with a sufficiently regular updates on JACIE activities. A first edition of the JACIE e-bulletin has subsequently been produced in August 2005. A copy is included in the supporting documentation submitted with this report. Copies of the EBMT News articles and slides from the Board meeting are included as supporting documentation under WP 11.1 and WP 5.1 respectively.

Deliverable 7	**Establishment and operation of training courses**
Work packages	**7.1** Development of training materials and exams **7.2** Delivery of 2 Centre Training Courses (Quality Management) for 50 healthcare professionals in centres preparing to be accredited (end January) **7.3** Delivery of 1 QMS Training Course at ISCT meeting in May for 30 laboratory professionals **7.4** Delivery of 1 JACIE Inspectors training course for 30 medical professionals **7.5** Development of modular training packs (comprising stand alone units accompanied by instructions to allow for delivery by non-professional trainers)

The development of modular training programmes and the delivery of Quality Management and Inspector training courses as part of the project were central to the objectives of:

- *Establishing equivalent JACIE training courses for medical professionals and inspectors across the Community and to facilitate the exchange of experience and best practice between them*
- *Implementation of JACIE Standards in haematopoietic stem cell facilities*

These activities also contribute towards the objectives of implementing JACIE standards in HSCT facilities and to the promotion of the JACIE programme amongst medical professionals with a view to encouraging harmonisation of standards and systems of accreditation across Europe.

A great success of the "JACIE" project in 2004 was to produce the modular training programmes and deliver the four training courses (3 Quality Management and 1 Inspector) planned, with full attendance on all courses, as detailed below.

Training materials and inspector exam:
Kerteza Professional Trainers in the Netherlands were selected by JACIE to assist in the development and delivery of the JACIE training courses planned as part of the project. Kerteza were selected based on their previous experience as consultants on the implementation of JACIE in Dutch transplant centres.

Kerteza, in consultation with the JACIE Office and members of the JACIE Executive Committee, developed course programmes and training materials for two types of training course:

1. **A training course in preparing a Quality Management System according to JACIE Standards:** This course was developed for healthcare professionals in transplant units preparing for inspection.
2. **An Inspector training course:** This course was designed to prepare healthcare professionals working in the field of transplantation to carry out peer-review inspections in other transplant centres either in their own country or in countries sharing the same language.

The training materials were developed in modular packs to enable them to be adapted to need for future training courses. Training scripts were also produced to enable delivery of the training courses by non-professional trainers. Copies of the 4 training courses (detailed below) delivered in 2004 are included as part of the supporting documentation submitted with this report and on CD (WP 7.1, 7.2, 7.3, 7.4 and 7.5).

Criteria for qualification as a JACIE inspector were drawn up by the JACIE Office, in liaison with FACT and an exam was produced for the inspector training course in May 2004. Copies of the criteria and the exam are included in the supporting documentation submitted with this report (WP 7.1: Training materials and exam).

Training courses:

As planned, in January 2004 two Quality Management courses were organised for healthcare professionals in transplant centres preparing for JACIE inspection.

The courses were held over two days and were attended by a total of 50 healthcare professionals:
21 - 22 January, Barcelona (25 attendees)
23 – 24 January, Barcelona (25 attendees)

The two Quality Management courses were organised back to back in order to reduce costs.
The courses were delivered by Kerteza training, supported by experts in the field of collection, processing and transplantation of haematopoietic stem cells.

Course evaluation forms were completed by the 50 participants (100%) and both courses were highly evaluated by 84% of participants.

A one and half day Quality Management training course was organised by ISCT, in collaboration with the JACIE Office, in Dublin on 10 – 11 May (25 attendees). Evaluations were completed by 100% of participants.

A two-day Inspector training course organised by the JACIE Office was held in Barcelona on 21-22 May 2004. There were 30 attendees, which represents 100% of planned participation. Course evaluation forms were completed by 28 participants (93%). In terms of satisfaction, 81% of participants rated the course as highly satisfactory while 15% rated the course as moderately satisfactory. Exams were completed by 27 participants and 25 were subsequently appointed as JACIE inspectors, following completion of a registration form and submission of CV and appropriate certification of medical qualification.

Overviews of the evaluation of each course and of the exam results from the Inspector training course are included in the appendices submitted with this report (WP 7.2, 7.3 and 7.4).

Participants on each course were provided with the following documents as budgeted for:

- Copy of JACIE Standards
- Guidelines to JACIE Accreditation for Applicants and Inspectors
- A complete course syllabus, with the training programme schedule, slides of presentation and background information referred to during the courses.

Contribution to stated objectives

The training materials and Kerteza trainers were highly rated and subsequently employed for a JACIE Inspector training course organised by the British transplant society in September 2004 and in a JACIE

Inspector training course organised by the Greek transplant society in September 2005. The training materials on Quality Management were used for reference purposes in producing the course documentation for a JACIE Quality Management course organised by GETH, the Spanish Transplant Society in May 2005 and the core materials will be used in a JACIE Quality Management course organised by the Greek JACIE National Representative, with the support of the Greek Transplant Society in November 2005. The use of these materials and Kerteza trainers in subsequent courses is testimony to the value of the materials and the professional training skills offered by Kerteza trainers.

The training courses organised in 2004 were attended by 105 medical professionals from across Europe, who came together to learn about Standards and Quality Management in the field of tissues and cell transplantation. These professionals came from different backgrounds (clinical, collection and processing) and the courses proved an excellent opportunity for sharing of best practice between different disciplines and countries. Sample plans for implementing a Quality Management systems have subsequently been incorporated into the model materials for sharing best practice (refer to WP 3.3). It was particularly notable that participants from the collection and laboratory processing setting had more knowledge and experience of quality management, which they were able to share with their colleagues with a clinical background, who had not been exposed to quality systems to the same level up until then.

Many of the participants on the Quality Management courses went onto successfully prepare their transplant programme for JACIE inspection in 2004. The courses have also contributed to a growing awareness and understanding of quality systems amongst healthcare professionals in the field and will have contributed to capacity building for implementation of the EU Directive.

Common training courses and exams should help to ensure that the JACIE accreditation programme is applied with equal rigour throughout Europe and thereby contribute to the overall harmonisation of standards and systems of accreditation.

The JACIE Office maintains an overview of the training provided for JACIE inspectors and keeps an up to date list and database of contact details for all trained JACIE inspectors. JACIE inspectors are classified according to their nationality, areas of expertise and languages. Only inspectors who have completed a JACIE training course and go onto successfully pass the exam and submit the necessary documentation will qualify as JACIE inspectors. JACIE currently has 85 certified inspectors available as a resource for implementing the JACIE programme in Europe. An overview is presented in the slide below. 191 medical professionals, in total, have participated in inspector training courses since 2000. The JACIE Office will continue to organise training courses and refresher courses on an annual basis in order to ensure that a substantial pool of well-qualified inspectors is available. JACIE is also working to identify gaps in training to ensure that there are sufficient qualified personnel to conduct inspections in the different countries and facilities.

EU Directive 2004/23/EC applies to collection and processing facilities manipulating haematopoietic stem cells and obliges Member States by April 2007 to put in place various control measures and be able to organise the inspection of relevant facilities. Member States must designate the competent authority(ies) responsible for implementing the new directive. By offering Member States an accreditation system which meets the requirements of the Directive, as well as a pool of qualified inspectors the JACIE programme hopes to play an integral role in the implementation of the Directive.

Inspectors by country

Country	Total	Clinical	Paed.	Collection	Paed.	Processing
Austria	2	1	0	0	0	1
Belgium	4	2	0	2	0	4
Denmark	3	1	0	2	0	2
Finland	4	2	1	0	0	1
France	7	3	1	1	2	2
Germany	1	1	0	0	0	0
Greece	1	1	0	1	0	0
Italy	11	4	3	2	0	4
Norway	2	0	0	2	0	2
Spain	3	2	0	0	0	0
Sweden	4	2	1	1	0	1
Switz.	9	7	1	5	0	2
Netherlan	10	3	0	4	0	5
Turkey	4	4	0	4	0	0
UK	20	9	4	8	0	8
Total	85					

Deliverable 8	**Implementation of pilot projects, innovative approaches**
Work packages	**8.1** Implementation of JACIE accreditation programme in 26 centres

The objective under WP 8 was a very clear one:

- *To implement the JACIE standards in health institutions and facilities involved in haematopoietic stem cell collection, processing and transplantation*

This objective was fundamental to the main aim of the project "to provide vital impetus to the JACIE programme and ensure its integral role in the inspection and accreditation of facilities involved in haematopoietic stem cell collection, processing and transplantation in Europe."

The "JACIE" project has succeeded very well in meeting this objective as illustrated by the activities conducted under this work package.

In the final quarter of 2003 the JACIE Office worked with JACIE National Representatives (JNRs) as planned to identify 26 centres that would be ready to apply for inspection in 2004. The JNRs also identified professionals from the different disciplines to train as inspectors at the May 2004 Inspector training course and participate in subsequent inspections.

25 inspections, including the pilot inspection organised by the Dutch partners, were conducted during the period of the action (from 01/01/2004 to 28/02/2005). A list of the centres and dates of inspection is summarised below. Inspections were held over one to one and a half days. Details of the inspectors who participated in the inspection are also provided in appendix x to the financial report.

	Applicant centre	Inspection date	City
	St. Anna Kinderspital	8-3-2004	Vienna
	St. Anna Kinderspital -PBSC Collection facility	27-9-2004	Vienna
	BMT Unit, First Medical Department, Medical University of Vienna	23-2-2005	Vienna
	Federation de Greffe de Moelle et de Therapie Cellulaire 'Auvergne	25-01-2005	Clemont-Ferrand
	Hôpital Henri Mondor	11-2-2005	Créteil
	Hôpital E. Herriot	9-4-2004	Lyon
	Hôpital Saint Louis	1-7-2004	Paris
	Hôpital Haut-Lévêque	30-9-2004	Bordeaux
	Institute G Roussy	17-12-2004	Villejuif
	University Medical Center St. Radboud	19-05-2004	Nijmegen
	Center of Onc/Hematology & Transfusion Medicine	9-11-2004	Aarau
	Kantonsspital Basel	26-1-2004	Basel
	Instituto Oncologie della Svizzera Italiana	21-9-2004	Bellinzona
	University Hospital Bern	27-1-2004	Bern
	Hôpital Cantonal Universitaire	28-1-2004	Geneva
	Programme Lausannois de Transplantation de Cellules Souches Hematopoietiques	24-11-2004	Lausanne
	Stiftung Zurcher Blutspendedienst SRK	5-4-2004	Schlieren, Zurich
	St. Gallen Kantonsspital	25-6-2004	St. Gallen
	Paediatric BMT Centre Zurich	1-10-2004	Zurich
	Zentrum fur Stammzelltransplantation Zurich	13-10-2004	Zurich
	Birmingham Heartlands Hospital	23/24-11-2004	Birmingham
	Bristol Royal Hospital for Children	25-6-2004	Bristol
	Yorkshire Blood and Bone Marrow Transplant Centre	28-6-2004	Leeds
	Nottingham City Hospital	5-10-2004	Nottingham
	The John Radcliffe Hospital Oxford	1-10-2004	Oxford

Following inspection, each Inspection Team Leader submitted an Inspection Report to the JACIE office. These reports were then reviewed by the JACIE Medical Consultant, who made a written recommendation to the JACIE Board regarding the level of preparation of the centre and any corrective action required prior to full accreditation. These reports have been compiled into a single document and are included in the appendices to this report (WP 8.1: Implementations of inspections and accreditations). Please note that the contents of the reports are confidential and should not be made public.

Of the 25 inspections, the outcome results were graded by the Medical Director as follows:

- **Level 1** **0 centres**
  No inspected centre achieved accreditation without further work
- **Level 2** **17 centres**
  Most centres demonstrated minor deficiencies which required some further work and submission of documentary evidence of the corrections
- **Level 3** **8 centres**
  A lower number of applicants demonstrated more critical deficiencies that required further work to rectify and submission of documentary evidence of the corrections and in of theses, two applicants required a focussed re-inspection by the original inspectors in order to affirm the corrections

The accreditation status of all centres currently participating in the JACIE programme can be consulted online at www.jacie.org

At the time of writing this report (October 2005) **13** of the **25** inspected centres have received JACIE accreditation. **2** centres fully comply with the Standards but must await EFI accreditation of their HLA typing laboratories before accreditation. **7** centres have submitted documentary evidence of deficiency correction identified by the inspection process and can expect to be accredited shortly. **2** centres are still in the process of correcting these deficiencies and reorganising their programmes. **1** centre, Nijmegen, was a pilot inspection so was not considered a formal application for accreditation. This will be applied for in the near future.

A survey completed by centres following each inspection visit illustrates that the inspection process was highly valuated by participating centres. The inspectors were rated to be highly professional by 95% of participating centres and 100% considered the inspection to be fair and objective. Although JACIE accreditation was found to be a huge strain on resources by the majority of participating centres accreditation was considered on balance to be worth it. See slides on following page with the relevant survey results presented at the EBMT annual meeting in Prague on 23 March.

The confidence of participating centres in the JACIE accreditation process is vital to the promotion and future success of the JACIE accreditation programme.

Survey of Centres
Results:7 Satisfaction

- Were you satisfied with the manner in which your centre was inspected?

Very satisfied	62%	Satisfied	38%

- Please rate the inspection team that visited your centre:

Highly professional	95%	Moderately professional	5%

- Do you consider that the inspection was fair and objective?

Yes	100%	No	0%

- How would you rate the quality of the inspection?

Profound & thorough	76%	Moderately detailed	24%

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- Do you consider that the inspection was fair and objective?

Yes	100%	No	0%

- How would you rate the quality of the inspection?

Profound & thorough	76%	Moderately detailed	24%

Contribution to stated objectives

Accreditation of a core number of centres as part of the "JACIE" project plays a strategic role in the promotion of the JACIE Standards and programme of accreditation. By demonstrating that the accreditation process is viable and has the full support of medical professionals in healthcare facilities that have undergone inspection, it serves to promote the Standards and programme with other HSC facilities and with healthcare authorities. The growing awareness and acceptance (including incorporation into national guidelines and legislation) of JACIE at the national level in a number of Member States is illustrated by the complied report produced by the JACIE Office "JACIE National Representative Survey, Spring 2005) included as supporting documentation under WP 9.1: Extension of JACIE Network of National Representatives. This demonstrates an integral role for JACIE within the overall framework for implementing standards and accreditation in the transplant field and will enable JACIE to continue to support the implementation of the EU Directive by acting as one of the competent authorities in some Member States, which choose to adopt JACIE in order to fulfil the requirements of the EU Directive.

C. Establishment and development of networks

Deliverable 9	**Creation and operation of networks and platforms**
Work packages	**9.1** Eight Applicant Countries and four additional Member States brought into the JACIE Network **9.2** Development of collaboration with national heath authorities

An important objective of this project was the strengthening and development of the JACIE national network. The aim during 2004 was to bring a number of new EU-member states and candidate countries, as well as Member States not formally represented on JACIE, into the JACIE network (13 countries) and to achieve the appointment of JACIE National Representatives to liaise with national health authorities and promote JACIE among fellow-professionals.

Another objective was to enhance the effectiveness of the existing JACIE network. This involved increased interaction between JACIE National Representatives and national health authorities to increase their understanding and involvement in JACIE. This objective in many ways overlaps with the activities under Work Packages 5 and 6 for collecting and disseminating data, as well as the production and distribution of JACIE Information Packs under Work Package 3.1. These materials have proved instrumental in enabling JACIE National Representatives to present the JACIE Standards and EU Directive to national representatives and national authorities in an effective manner.

Activities

At the 2004 EBMT Annual Meeting in Barcelona at the end of March, a meeting was held for medical professionals from countries outside of the existing JACIE network in order to update them on the

development of JACIE and also to allow them to outline their national situations and requirements for approaching accreditation. A copy of the invitation letter, attendance list and slides presented at the meeting are included as supporting documents in the appendices under WP 9.1: Extension of JACIE network. Participants were asked to liaise with their colleagues and national transplant societies (where they exist) in order to appoint an official JACIE National Representative. A follow-up meeting was held at the annual meeting in Prague on 21 March 2005. Copies of the JACIE Manual and Information Packs were shared with participants and the contents of the directive and information leaflet elaborated upon.

7 new JACIE National Representatives have been appointed since the outset of the "JACIE" project. A list of these representatives is included as supporting documentation in WP 9.1. In Croatia, two doctors have attended JACIE inspector training course and a presentation on JACIE was delivered at the National Group for Haematology and Transfusion Medicine in September 2004 and the society is currently discussing appointment of a JACIE National Representative.

The full list of countries officially represented on JACIE is summarised below.

Countries currently with JACIE National Representatives

(*New Member States and Applicant Countries)

Austria	Germany	Slovenia*
Belgium	Greece	Spain
Czech Republic*	Italy	Sweden
Denmark	The Netherlands	Switzerland
Estonia*	Norway	Turkey*
Finland	Poland*	United Kingdom
France	Slovakia*	

The number of newly appointed JACIE National Representatives falls short of the projected 12. This was in part due to limited resources available within the JACIE Office to establish a regular contact with representatives in the non-network countries. Another problem is that the absence of a national transplant society in a number of countries makes the process of appointing a national representative more problematic. In these countries transplant centres many need to come together to form a national society before they are able to take JACIE forward in an official way.

The National Representatives of the 13 countries currently in the existing JACIE network have been in liaison with their national societies and health authorities throughout 2004. There has been particularly active involvement with the authorities in those countries where inspections have been carried out in 2004, namely UK, Switzerland, France, Italy and the Netherlands. Country specific reports were made by National Representatives at the October Board meeting and this was followed by an online survey of national representatives at the end of the project to evaluate the following:

- contact with national authorities
- recognition of JACIE in national legislation

- support for JACIE from that national health authorities
- other accreditation bodies working in the field
- citing of JACIE in official publications
- support for JACIE from the national transplant or hematology society

A compiled report on the outcomes of that survey is included as supporting document in the appendices to this report (WP 9.2: Collaboration with national authorities).

Contribution to stated objectives

• It was stated in the original project proposal that increased collaboration with health authorities would be demonstrated by official acceptance of the JACIE standards and accreditation programme. JACIE used its network of JACIE National Representatives to establish contacts with health authorities in their respective countries. Each Representative was asked to present JACIE to the relevant department or people concerned with implementation of the EU Directive 2004/23/EC and outline the work already carried out and explore the possibility of JACIE Standards and the JACIE Inspectorate being used to support the inspection procedures as required by the Directive. In overall terms, the results of these contacts succeeding in raising the profile of JACIE among health administrators although no authority wished to adopt JACIE wholesale, preferring to consider JACIE in the context of other accreditation bodies.

The specific position of JACIE in each country at the end of the project is outlined in detail in the National Representatives' Survey carried out last March but some further developments have taken place since the formal close of the project in March 2005. These developments are a reflection of the sound base established in 2004 and 2005 which has built JACIE's credibility and capacity. Some advances include:

• The Netherlands where as part of a government project, the well-established CCKL agency, responsible for managing compulsory accreditation of laboratories has incorporated JACIE Standards into its accreditation programme.

• In Belgium, JACIE inspectors will be invited to act as advisors to the Ministry of Health on implementing the EU Directive.

• In the UK, JACIE has been in regular contact with the Department of Health. JACIE is specifically cited in the National Institute of Clinical Excellence (NICE) 'Improving Outcomes in Haematological Cancers' guidance and states that "The guidance recommends that high dose therapy and stem cell rescue should be provided only in specialist centres which meet JACIE accreditation standards for bone marrow transplantation (BMT)".

• In Italy, the Centro Nazionale Trapianti (CNT) represents the Competent Authority for the Safety and Quality of tissues and cells defined by the EU directive 2004/23/EC. As an agency of the Ministry of Health, the CNT supports the implementation of JACIE Standards among BMT programmes and is willing to delegate JACIE to perform inspections of HSC transplant programmes and to consider

JACIE accreditation equivalent to CNT accreditation. The CNT will ask that JACIE inspectors guarantee that all the EU directive requirements are checked during the inspections.

- In Poland, the Ministry of Health is planning to support accreditation expenses within the scope of POLGRAFT programme in 2006.

Overall, it was felt that national heath authorities are addressing the issue of implementing the Directive only now and that where there was little or no interest in the past, so previous contacts over 2004 and 2005 may now start to pay dividends. This has been the case in Sweden where JACIE is now held up as an example of self-organisation (by the stem cell community) to other transplanters e.g. tissues, organs. In Switzerland, where all 10 teams were inspected and 7 accredited through the JACIE project, a new law on transplantation, effective from 1 January 2007, will make JACIE mandatory for HSCT teams.

D. Information and learning

Deliverable 10	**Evaluation and assessment of specific issues carried out**
Work packages	**10.1** Analysis of common *difficulties* in the accreditation process **10.2** Analysis of common *deficiencies* in implementation of standards **10.3** Analysis of the *impact* of implementation of JACIE

An important objective of any project is to evaluate the results of project activities. In the case of the "JACIE" project it was felt very important to analyse the difficulties encountered by transplant facilities participating in the JACIE accreditation programme and to analyse the deficiencies in implementation of the JACIE Standards identified by the inspection process. These analyses feed into the ongoing development of the accreditation programme, as well as into the content of training courses and materials to help healthcare professionals prepare their facilities for accreditation.

An analysis of the impact of going through the process of accreditation was felt to be valuable from the point of view of communicating the results of the "JACIE" project and for promoting the programme among health professionals, national authorities and for building public confidence.

Analysis of common difficulties

A centre survey to analyse common difficulties identified in the accreditation process was prepared by the Project Officer in September 2004 and presented as an online survey on the JACIE Online system. All centres inspected in 2004 were asked to complete and submit the survey. An analysis of the results was carried out by the Medical consultant and a report on Common Difficulties was produced in February. Copies of the survey, analysis and final report are included as supporting documents in the appendices to this report (WP 10.1 Analysis of common difficulties in the accreditation process). The conclusions are included below for ease of reference:

"The results of the survey are consistent with the findings of the inspectors (see Common Deficiencies section) that the most common deficiencies are inadequacies in the quality management system, particularly in the clinical

programme. The survey also indicates that these arise from lack of trained staff and absence of QM culture in the clinical setting.

There is clearly an important need for training of clinical staff (doctors and nurses) in quality management. One of the major aims of JACIE over the next 1-2 years is provision of more educational material such as model documents and a guide to implementing QMS in a transplant centre.

At a local and national level, resources must be made available to enable centres to comply with the guidelines, in particular to employ a dedicated quality manager, at least on a part-time basis".

Analysis of common deficiencies

As part of the inspection process, inspectors were required to record common deficiencies to be included as part of the inspection report. These were analysed by the Medical Consultant in the process of preparing the Consultant Recommendation report to the main Board. The deficiencies identified by the inspectors were compiled into a single document, which formed the basis of the Medical Consultants report on common deficiencies produced in February. A copy of the Accreditation Deficiencies compilation report and the final report on common deficiencies are included as supporting documents in the appendices to this report (WP 10.2 Analysis of Common Deficiencies). The conclusions are included below for ease of reference:

"The analysis of common deficiencies shows that quality management in the clinical area and component labelling are the most frequently observed sources of deficiencies. The frequency of deficiencies involving quality management and adverse event reporting are consistent with the reported difficulties experienced by centres (see Common Difficulties section).

As noted above, there is a need for training of clinical staff (doctors and nurses) in quality management. It is also important for centres to have a designated quality manager who has appropriate experience in quality management systems.

Problems with designing suitable component labels are currently being addressed by the International Labelling Working Party. The identification of labelling as a frequent area of non-compliance was one of the major reasons for establishing this working group."

Impact of implementation of JACIE

A survey was prepared in September 2004 to analyse the impact of implementing JACIE. Centres that had undergone inspection in 2004 were asked to complete the survey 6 months post-inspection to assess the changes introduced and improvements noted as a result of implementing the JACIE Standards in the following areas:

- Control of incidents, events and adverse reactions
- Data management
- Internal coordination

- Patient satisfaction
- Staff motivation
- Costs
- Facilities
- Patient safety and care
- Procedures and practice
- Training of staff
- Compliance with health insurers'/social security demands
- Government recognition

Centres were asked to identify whether the Quality Management system now in place had brought to light any need for changes in the programme, whether accreditation was worth the effort and if measures had been put in place in order to maintain the levels required for JACIE accreditation. At the end of February 2004 8 centres were in a position to complete the survey. The Medical Consultant therefore produced an interim report based on the 8 surveys. A follow-up was subsequently carried out by the JACIE Office and now 20 centres have completed the survey and the Medical Consultant is the process of assessing the results to feed into a final report and publication on the impact of JACIE accreditation.

Copies of the questionnaire and interim report are included as supporting documents in the appendices to this report (WP 10.3 Analysis of impact of Implementation of JACIE). The initial conclusions drawn are included below for ease of reference:

"Despite the difficulties experienced by centres in implementing JACIE there is no doubt that they felt the effort was worth it and that their programme had benefited from the process. There is also no doubt that additional resources are needed on an ongoing basis once the standards have been implemented. In the future there is a need to assess the effect of implementation on a more formal basis, using for example analyses of adverse events and patient satisfaction questionnaires in order to allow a cost-benefit analysis of JACIE implementation."

Contribution to stated objectives

These analysis and reports allow us to positively evaluate the JACIE accreditation programme and the activities carried out under the "JACIE" project. They also provide important data which feeds into the ongoing development of the Standards and into training course and model materials for sharing of best practice.

In addition, as commented under contribution to stated objectives under Work package 8:
"By demonstrating that the accreditation process is viable and has the full support of medical professionals in healthcare facilities that have undergone inspection, it serves to promote the Standards and programme with other HSC facilities and with healthcare authorities."

Deliverable 11	**Preparation of reports and publications**
Work packages	**11.1** Report on the project's impact on the implementation and harmonisation of standards in Europe **11.2** Assessment report on the use of EBMT and JACIE data in monitoring standards **11.3** Announcement of project in relevant media: Press releases to inform the general public; dissemination via EBMT News and website; submission of articles on JACIE to professional journals

The objective of the deliverables of this Work Package was:

- *To promote the JACIE programme among the scientific community, medical professionals, national authorities, Community officials and the general public with a view to encouraging harmonisation of standards and systems of accreditation across the EU*

11.1 Report on project's impact

An interim report on progress of the JACIE project, including aspects of harmonisation and progress at the national level was made at the JACIE Board meeting on 7 October 2004. A complete set of slides presented at that meeting is included in the supporting document in the appendices to this report (WP 4.1: Functioning JACIE Office). A final report was presented at the JACIE Board meeting on 20 March 2005. A complete set of slides presented at that meeting is included in the supporting document in the appendices to this report (WP 11: Preparation of reports and publications).

This final implementation report and supporting documents represents a compilation of the feedback received from the various stakeholders and of all relevant information on the implementation of JACIE Standards and programme of accreditation arising from the JACIE" project. Data held on JACIE online has formed the basis of this report.

11.2 Assessment report on the use of EBMT and JACIE data in monitoring standards

There has not been the opportunity for personnel from the JACIE Office and the EBMT registry Office to sit down together and closely review the contents of both databases in order to produce a formal report on how the data in the EBMT Registry and JACIE Online can be used to monitor the impact of implementing Standards in transplant centres. Informal discussions have however been held and clear opportunities have been identified. A report on the relationship between the "Relationship between the data collected by the EBMT and JACIE" is included in the supporting documentation submitted with this report under Management documentation and is updated with the following information.

Over the course of 2004 a new relational database was incorporated into the EBMT ProMISe system, which is the central registry for the EBMT and a number of affiliated national registries. The new database holds separate data on transplants and on centres performing these transplants. A virtually unlimited number of fields can be created in both of these databases and important quality checks

are built into the new system. As the two databases are fully relational data on centres and transplants can be subject to comparative analysis.

18 of the 19 countries within the current JACIE network have accepted to administer the JACIE accreditation process via the online system, meaning that the data on each inspection in these countries will be comparable across Member States.

This will allow the EBMT to incorporate key indicators on accreditation from the JACIE Online system into membership database on ProMISe:

- Date of initial application
- Date of inspection
- Date of accreditation award
- Date of accreditation renewal and subsequent accreditation awards

The data on accreditation can then be analysed against the transplant data of accredited centres held on the system in a statistically significant manner. The time dependent covariates on accreditation allow for analysis of outcome measures such as transplant related mortality and morbidity. It is also possible to analyse economic indicators such as the amount of time spent in hospital.

These analyse could be carried out at the European level by the EBMT or at the national level by the national registries affiliated to the EBMT (Italy, France, The Netherlands, Germany, Austria, UK, Czech Swiss and Spanish). The value of such analysis maybe currently limited given the number of centres who have gone through the process of accreditation to date. However, in future years when the majority of EBMT centres will hopefully have gone through the process of JACIE accreditation such analysis could prove very valuable. The interest in incorporating the JACIE data into the EBMT database and of performing these analyses will be explored further within the EBMT and the National Societies.

11.3 Announcement of project in relevant media

It was originally intended to launch the "JACIE" project with a press release announcing commencement of the grant award and official launch of the project. The late signature of the contract agreement made this inappropriate due to timing. Once the Commission has had the opportunity to sign off on the final implementation report and financial report it is intended to submit a press release announcing the successful completion of the project and highlighting the measures being taken at the EU level in relation to the implementation of Standards for human tissues and cells. A draft of the press release will be submitted to the Commission for approval, before sending it to JACIE National Representatives for translation and circulation to relevant media in their respective countries.

Every opportunity has been used to take advantage of the EBMT communication platform (newsletters, website bulletins and annual meetings) to disseminate information on the JACIE project to medical professionals in the field.

JACIE project reports were published in the March, July and November editions of EBMT News. A report on the EU Tissues and Cells Directive was also written for the July edition of EBMT News and for the FECs (Federation of European Cancer Societies) Newsletter (July 2004). Copies of these articles are included in the appendices to this report (WP 11.3 Announcement of project in relevant media).

An abstract on JACIE activities in 2004 was submitted to the 10th European Forum on Quality Improvement in Health Care organised in the UK in April 2004 and is included in the appendices to this report (WP 11.3).

JACIE accreditation featured in the programme for the March 2004 EBMT Annual Meeting held in Barcelona. This included presentations by BMT centres that had applied for JACIE Accreditation under the following headings:

Supportive care / Regulatory issues

- Method to comply with the JACIE standards on qualification of staff involved in stem cell transplantation
- Implementation of a total quality management programme in peripheral blood and bone marrow transplantation – beyond accreditation
- JACIE quality management refers to an integrated programme of quality assessment, assurance, control and improvement. How can it be set up transplant units?
- Implementing the detection and evaluation of adverse events following JACIE standards

JACIE Accreditation also featured prominently in the scientific programme of the EBMT annual meeting held from 20 – 23 March in Prague. Seven abstracts and two posters on JACIE were accepted for presentation at the meeting. The following sessions involving JACIE were central to the meeting:

Nursing sessions

- Nurse experience in quality management of haematopoietic stem cell transplant patients: benefits of JACIE accreditation
- Including the multidisciplinary team: integrating nurses and allied healthcare professionals into JACIE accreditation guidelines
- JACIE - impact for nurse
- JACIE accreditation approach: a single-centre experience
- Allogeneic donor safety: addressing JACIE
-

Regulatory issues / Stem cell donor

- The JACIE accreditation programme: experience after the first year of full implementation
- JACIE-standards for haematopoietic stem cell transplantation: benefits and costs

Joint Session EBMT / WMDA / ISCT: Regulatory issues

- Regulation of haematopoietic stem cell transplantation - globalisation versus separatism
- Accreditation of haematopoietic stem cell transplant facilities
- Accreditation of stem cell collection and storage facilities
- Accreditation of unrelated donor registries

Copies of all the abstracts presented are included in the appendices to this report (WP 11.3).

A number of articles directly related to implementation of the "JACIE" project have been published in peer review journals to increase the awareness and understanding of the JACIE programme among the scientific community:

- *Implementation of the JACIE standards for a haematopoietic progenitor cell transplantation programme: a cost analysis. Zahnd D, Leibundgut K, Zenhausern R, Pabst T, Fontana S, Schneider R, Tobler A, Zwicky C. Bone Marrow Transplantation. 2004 Nov;34(10):847-53.*
- *Just Another Cost Increasing Exercise (JACIE)? Apperley J. Bone Marrow Transplantation 2004 Nov;34(10):835-8*

There have also been a number of related articles on JACIE published during the course of the project, which highlight quality management issues and the role of the JACIE programme to relevant members of the scientific community.

Related publications (2004_2005)

- *Who will regulate the regulators? J M Goldman. Bone Marrow Transplantation (2004) 34, 1013-1014*
- *What Is Quality in a Transplant Program? C. Fred LeMaistre, Fausto R. Loberiza, Jr. Biology of Blood and Marrow Transplantation 11:241-246 (2005).*
- *Real-time process/quality control for HPC processing. Arpagaus M, Leibundgut EO, Zbaren K, Brunold C, Ischi E, Tobler A, Zwicky C. Cytotherapy. 2004;6(5):505-13.*
- *Stem-cell harvesting and manipulation. D. Pamphilon. Vox Sanguinis Volume 87 Issue s1 Page 20 - June 2004*
- *'Requirements for a clinical BMT Unit, A Urbano'. Chapter 4. Haematopoietic Stem Cell Transplantation, 2004 revised edition. EBMT & ESH*
- *Impact of regulations on translational research in cell and gene therapy: the US experience. Raphaël F. Rousseau, Adrian P. Gee. (French). Bulletin du Cancer. Number 91, volume 3, 239-47, MARS 2004*
- *Outbreaks of infectious diseases in stem cell transplant units: a silent cause of death for patients and transplant programmes. McCann S, Byrne JL, Rovira M, Shaw P, Ribaud P, Sica S, Volin L, Olavarria E, Mackinnon S, Trabasso P, VanLint MT, Ljungman P, Ward K, Browne P, Gratwohl A, Widmer AF, Cordonnier C; Infectious Diseases Working Party of the EBMT. Bone Marrow Transplant. 2004 Mar;33(5):519-29*

It is intended to submit an article reporting on the experience of the JACIE programme and its role in standard setting, inspection and accreditation in the field of haematopoietic stem cell collection, processing and transplantation. This article will incorporate information from the reports on common difficulties, common deficiencies and analysis of the impact of implementation of JACIE, as well as from the survey of JACIE National Representatives (submitted as supporting document to this report under WP 9.2 and WP 10.1/2/3). This article has not yet been finalised, because the data related to the analysis of the impact of implementation was not complete until the end of September. This analysis is based on the centre survey carried out under Work Package 8.1 Implementation of inspections and accreditation. This was a survey which was completed by centres 6 months post-inspection. As the last inspection was completed in February, the final data could not be completed until September 2005. There is now sufficient data to allow an analysis for publication in a peer-review journal. The Medical Consultant will produce the report by mid November and the article will be submitted for publication in Bone Marrow Transplantation journal. As BMT journal is now the Official Journal of the EBMT, the article will be fast tracked for publication. A copy of the article will be submitted to the Commission before the end of November for review.

Contribution to stated objectives

The profile of JACIE among the HPC transplant community has been raised by this project through dissemination via printed articles, web site updates, training courses and presentations/workshops. The success of this promotion is reflected in demand for places on training courses and requests for information in addition to applications for accreditation. Since the finalisation of the project in March 2005, 12 further applications have been received from SCT transplant programmes. Increasing interest among health authorities as detailed above is also testimony to the promotion work undertaken by national representatives in their respective countries. JACIE's interaction with the EU Commission in the area of the Technical Annexes of the Directive 2004/23/EC and with the Council of Europe as part of their Experts Committee on Safety and Quality Assurance for Organs, Tissues and Cells show the success of JACIE in establishing itself as a recognised authority in the area of quality management in stem cell harvesting, processing and transplantation.

2. Manpower for execution of the activities

As this section of the report was completed in excel format an overview and detailed breakdown of the following data are submitted as **annex 1** to this report:

- list of persons who participated
- man days of work
- professional level or category
- corresponding unit and total cost
- partner or organization to which person belongs
- activities performed by each person

The overview includes the names of the key persons responsible for delivering the project or where it was not possible to list all the participants the corresponding group description: JACIE National Representative, Board members, Inspectors and Centres. In each of these cases there were no costs associated with the activities performed as all of the members of these groups were medical professionals who gave their time to the project free of charge. The professional level or category of each participant is also given.

What is clear from this data is that the professionals participating in the project gave a substantial amount of time to the project and that the real costs in terms of professional time dedicated to this project are not reflected in the relatively limited project budget. For this reason the number of actual days against projected days is so high. This requires appreciation of the dedication and commitment of these medical professionals to the "JACIE" project and programme of JACIE accreditation as a whole. This can be illustrated with reference to the inspections performed as part of the project. 75 inspectors dedicated at least 2 days of their time to inspection preparation, on-site inspection and reporting. Based on the costs of the Medical Consultant, it can be estimated that the time of each inspector could be charged at 375€ per day. The full costs of these professionals for their contribution to the project could therefore be estimated at 56,250€.

The activities of each person or group are summarised by Work Package and in the appendix details of the Work Packages are listed. Full reference to the Work Packages are made in this Final Implementation report and in the accompanying Financial Report making it clear how each key person or group contributed to the activities and objectives of the project.

A comparison is given below of how the data on manpower (for those persons with budgetary costs associated) compared with the original proposal and as reflected in appendix 1 and the financial report.

Person	Original proposal	Financial report	Explanation
Fiona Mc Donald, Project Manager	90 days at a cost of 20.488,65€	92 days at a cost of 19.536,71€	Extra work on reporting, but final salary slightly lower than budgeted.
Eoin Mc Grath, Project Officer	110 days at a cost of14.410,00€	115 days at a cost of 15.566,54€	Extra work on developing procedures and IT system.
Sara Notley, Administrative Assistant	110 days at a cost of 13.7500€	110 days at a cost of 13.296,02€	
Dr Diana Samson, Medical Consultant	50 days at a cost of 18.750,00€	55 days at a cost of 22.163,173€	Additional time was spent on liaison work (European Council, FACT) than anticipated. In addition VAT was added to the fee of 375€, resulting in a higher than anticipated unit cost.
Marij Verlinden, Treasury Assistant	40 days at a cost of 5000€	40 days at a cost of 6607,67€	Salary slightly higher than originally budgeted.
Lee Buckler, ISCT Executive Officer	No financial provision made	0,00€	0,00€
Patrick Corstiaans and Freek van Ham, Kerteza Trainers	A set number of days work and fee of 1250€ per day were set in advance of the project. Both the number of days work and unit cost were respected in the delivery of course outlines, training packs, model materials and training courses. 1250€ per day for 23.5 days at a total cost to the project 29.375,00€	29.374,00€	
Polymita Technologies	A fixed fee of 58.477,92€ was set for the delivery of the IT system and this was agreed in advance of the project.	58.651,92€	Variance minimal
Sylvia Gaillard,	A designer was employed to carry	38.608,67€	29.050,00€

Designer	out the design work on the JACIE Manual , Standard, Information Pack and general stationery. This was not originally anticipated in the project, but was felt necessary in order to create a brand image separate from the participating organisations EBMT and ISCT and to reduce the workload on the JACIE Office. These additional costs are reflected in the additional costs indicated for print materials under Misc. inspections.		The additional costs are not claimed as an eligible cost of the project and are borne by the EBMT.

3. Partners involved

Further details of the participation of the project partners is presented in section 1 of this report. The following is a general overview.

The EBMT was the main partner on this project and was fully responsible for coordinating the activities of the other partners. As indicated in the original proposal the International Society for Cellular Therapy (ISCT) and a number of national transplant / haematology societies acted as partners on this project. A number of these national societies also acted as Associate Beneficiaries or made a financial contribution to the project:

- The Belgian Hematalogical Society (BHS)
- Sociéte Francaise de Greffe de Moell et Thérapie Celluliare (SFGM-TC)
- Dutch National Registry (TYPHON)
- Grupo Español de Transplante Hematopoyetico (GETH)
- The Swedish Hematological Society
- The British Society of Blood and Marrow Transplantation (BSBMT)
- Gruppo Italiano Trapianti Midollo Osseo (GITMO)
- Swiss Bone Marrow Donor Registry (SBMDR)

Each of the above appointed a National Representative. All JACIE National Representatives are automatically members of the JACIE Board and attend JACIE Board meetings twice a year. The JACIE Board is the final decision-making body of JACIE. In addition the Representatives provided assistance with inspections in their country, nominated attendees for training courses and promoted JACIE among fellow professionals and health authorities.

Limited input with no financial support was also received from:

- German National Registry
- The Austrian SCT Registry (ASCTR)
- Swiss Transplant Society (STABMT)

The following societies as new members of the JACIE Network appointed National Representatives in 2004/5

- Turkish Society of Hematology
- Czech Society of Hematology
- Polish Society of Haematology and Transfusion Medicine
- Slovak Society of Haematology and Transfusiology
- Greek National Organization for Transplantation

National Representatives were appointed for the following countries where no national haematology society exists:

- Slovenia
- Estonia

ISCT

The role of ISC T in this project was limited to the organisation of a JACIE Quality Management training course held in Dublin on 10-11 May 2004 and the setup of the JACIE Online Forum.

The course was held alongside the ISCT annual meeting in order to keep costs to a minimum for the organisers and participants. ISCT were responsible for the logistical arrangements of this meeting (promotion of meeting and registration of delegates, room rental, technical support and printing costs). The course materials delivered were developed by the EBMT as part of this project in collaboration with Kerteza professional trainers, who were responsible for delivering the ICST training course. This ensured that the course was in-line with JACIE requirements. The course contributed to the objectives as explained under WP 7 of this report.

The JACIE Online Forum was set up by the ISCT web manager. It was initially launched in a basic format but in August 2005, the forum was re-launched with added functionality and improved design. This work was undertaken as a contribution in kind to the JACIE project by ISCT.

4. Countries involved

Country	JACIE Network member	Activities
Austria	Existing member	3 inspections in 2004/5. 1 centre accredited and 1 centre in final phase 2 inspectors trained Contacts with health authorities
Belgium	Existing member	4 inspectors trained JACIE working party formed Contacts with health authorities
Czech Republic	New member	Up to 3 applications expected in 2005/6 Contact with health authorities
Denmark	Existing member	3 inspectors trained
Estonia	New member	-
Finland	Existing member	4 inspectors trained Contacts with health authorities 4 presentations at national meetings 4 applications for accreditation 2005-2006
France	Existing member	6 centres inspected 3 centres accredited and 3 in final phases 7 inspectors trained Contacts with health authorities
Germany	Existing member	1 inspector trained JACIE managed a national level via German Registry (DAG-KBT) 25 applications for JACIE accreditation 1 presentation at national meeting
Greece	New member	1 inspector trained 13 BMT programmes cooperating at national level to prepare for JACIE Contacts with health authorities
Italy	Existing member	11 inspectors trained Contacts with health authorities and support for using JACIE inspectorate to implement Directive 6 applications for accreditation 2005/6
The Netherlands	Existing member	10 inspectors trained Contacts with health authorities Support from ministry of health

Norway	Existing member	2 inspectors trained
Poland	New member	Contacts with health authorities Support from ministry of health 15 applications for accreditation 2005-2008
Slovakia	New member	Contacts with health authorities
Slovenia	New member	-
Spain	Existing member	2 inspectors trained Contacts with health authorities
Sweden	Existing member	3 inspectors trained Contacts with health authorities
Switzerland	Existing member	All 10 BMT programmes inspected 7 accredited with 3 in final phase Contacts with health authorities JACIE accreditation required by law for HSCT teams from 2007
Turkey	New member	4 inspectors trained Contacts with health authorities
United Kingdom	Existing member	5 inspections in 2004 3 accredited with 2 in final phase 20 inspectors trained 8-10 applications for accreditation 2005-2007

5. Achievement of objectives

The contribution of project activities to stated objectives have already been elaborated upon at some length in section 1 of this report, therefore the details and references to supporting documentation included with the report is not repeated here and this section is intended as a summary conclusion. Cross-referencing of the Work Packages is given for the reader's ease.

This section is structured by presenting the full list of objectives set in the original application and going on to evaluate the extent to which the activities under the various work packages have contributed towards achieving each objective. The monitoring, assessment and other evidence which forms the basis of the evaluation is also listed under each objective and where difficulties were encountered these are highlighted and explained.

Aims and objectives set in the original proposal:

The aims of the project are to provide vital impetus to the JACIE programme and ensure its integral role in standard setting, inspection and accreditation for health institutions and facilities involved in

haematopoietic stem cell collection, processing and transplantation in Europe. The specific objectives are:

1. To harmonise the JACIE standards and programme of accreditation with the Community Directive arising from COM (2002) 319 final and contribute to the ongoing development of technical standards and systems for quality and safety of human tissues and cells

2. To implement the JACIE standards in health institutions and facilities involved in haematopoietic stem cell collection, processing and transplantation in Member States

3. To promote the JACIE programme among the scientific community, medical professionals, national authorities, Community officials and the general public, with a view to encouraging harmonisation of standards and systems of accreditation across the Community

4. To strengthen the central resources for managing and administering the JACIE programme and to extend and enhance the effectiveness of the existing JACIE network

5. To establish equivalent JACIE training courses for medical professionals and inspectors across the Community and to facilitate the exchange of experience and best practice between them

6. To contribute to the comparability of data across Member States by supporting the existing network of EBMT and national registries in the collection of compatible and comparative transplant data

Evaluation:

1. Harmonisation of the JACIE standards and programme of accreditation with EU Directive 2004/23/EC

Activities under the following work packages have all contributed to ensuring that the JACIE standards are inline with the EU Directive and put the JACIE programme in a key position to play an integral role in standard setting, inspection and accreditation of facilities involved in stem cell collection, processing and transplantation in Europe.

- Development of quality measures and standards in specific areas (Work Package 1)
- Development of Guidelines in specific areas (Work Package 2)

The engagement of lead JACIE personnel with experts in the field in the Commission and Council of Europe over the development of the technical annexes to the Directive and other regulatory guidelines in the field demonstrates the value and expertise that JACIE has to contribute towards standards and accreditation in the field and the appreciation of this at the official level in Europe.

The 2nd edition of the JACIE Manual and standards, which have been widely distributed in HSC facilities throughout Europe, helps build awareness amongst medical professionals of standards and quality management and prepares them to meet the regulatory framework of the EU Directive, either through the application of JACIE or their eventual participation in other accreditation programmes adopted as the competent authorities by Member States under the Directive.

The JACIE programme continues to work towards harmonisation both at the EU and International level through its work on the JACIE/FACT standards committee. The goal of which is to produce a 3rd edition of the JACIE standards, reflecting the European reality and inline with the EU Directive. As the Northern Americans will employ the same standards harmonisation is widespread.

Monitoring, assessment and other evidence which forms the basis of this positive evaluation of the role of JACIE in the harmonisation process are:

- JACIE feedback on the first and second technical annexes to the EU Directive (WP 1.1)
- A sample copy and distribution list for the JACIE Manual, which incorporate the 2nd edition of the JACIE standards (WP 2)
- Increasing reference to JACIE within the context of the regulatory framework of the EU Directive, as illustrated by the JACIE National Representative survey (WP 9.2)

2. Implementation of JACIE standards and accreditation in haematopoietic stem cell (HSC) facilities

A considerable amount of time and resources of the project were invested in successfully implementing JACIE standards and accreditation programme in the 25 centres selected to participate in the project. The following activities contributed towards achieving this objective:

- The establishment of a JACIE Office (Work Package 4)
- Delivery of training courses and sharing of best practice (Work Package 7)
- Implementation of JACIE in HSC facilities (Work Package 8)

Centralisation of the JACIE programme through the establishment of a fully functioning European JACIE Office in Barcelona (Work Package 4) was essential for the delivery of the "JACIE" programme and for enabling delivery of training courses and implementation of JACIE in HSC facilities over the course of the project.

Prior to commencement of the project the JACIE accreditation programme was administered at the national level and was suffering from inertia. Early on in the project a JACIE Office, located alongside the EBMT Secretariat in Barcelona, was established through the recruitment and training of identified personnel and the appointment of a JACIE Board.

Taking advantage of the pre-existing resources, knowledge and communications platform within the EBMT Secretariat, the JACIE Office was able to quickly develop and put into operation the necessary processes for coordinating the various stages of the accreditation process (centre registration, document submission, allocation of inspection dates and inspectors, inspection visits, reporting and final sign off on accreditation). These processes fed into the development of the JACIE Online system, which now effectively automates the majority of the administrative procedures and facilitates the effective management of the JACIE programme.

Training course for centres preparing for inspection were delivered very early in the project (January 2004) to build participants' knowledge and understanding of Quality Management and the JACIE standards in order to facilitate their preparation for accreditation. Inspector training took place in May 2004 ensuring that there was a sufficient pool of qualified inspectors to participate in the inspection of the 25 centres participating in the project.

Between January 2004 and the end of February 2005, the JACIE Office managed the registration and documentation submission for 24 HSC facilities and coordinated 24 inspection visits, as well as the post inspection reporting, follow-up and awards of accreditation, where appropriate (Work Package 8). The Dutch partners organised and conducted a pilot inspection of an HSC facility in Njimegen and the inspection report was subsequently assessed by the JACIE Medical Consultant.

In the initial project proposal 27 inspection visits were planned. The completion of 25 inspections and corresponding follow-up during the course of the project reflects a considerable achievement of the project. Participation in the training courses and accreditation programme were both positively evaluated by participating individuals and centres respectively.

At the end of the project the JACIE programme is vibrant and fully functioning, with a dedicated staff, Board and pool of qualified inspectors. The implementation of the JACIE standards and programme is ongoing and the JACIE programme continues to go from strength to strength as illustrated by the interest in accreditation (12 HSC facilities inspected in 2005; registration of interest to be inspected in 2006 by a further 25 HSC facilities) and the growing support for JACIE accreditation at the national level as reported in the survey of national representatives.

Monitoring, assessment and other evidence which forms the basis of this positive evaluation are:

- The minutes of the JACIE Board meetings and the Annual Report of the EBMT, which demonstrate the activities and functioning of the JACIE Office and programme of accreditation (WP 4.1)
- The course evaluations completed by participants on the Quality Management and Inspector training courses (WP7.2, 7.3 and 7.4)
- The Medical Consultant's reports evaluating 25 inspected centres (WP 8.1) and the corresponding analysis report of Common Deficiencies (WP 10.2)

- The surveys completed by 20 inspected facilities post-inspection to evaluate common difficulties and the impact of implementing JACIE accreditation and the corresponding analysis reports produced by the Medical Consultant (WP 10.1 and 10.3)
- The JACIE national representative survey, demonstrating the growing interest in the JACIE programme at the national level in many countries

3. Promotion of JACIE amongst medical professionals, national authorities, Community officials, with a view to encouraging harmonisation of standards and systems of accreditation across the Community

Fulfilment of objective 1 was in many ways a precursor to achieving the aims under objective 3. Therefore the extent to which the JACIE project has sought to ensure that the JACIE standards are inline with the EU Directive have also served to promote JACIE and highlight the integral role the JACIE standards and programme of accreditation have to play in standard setting and inspections in the HSC field. In addition, the following work packages have contributed to promoting JACIE and making known the applicability of the EU Directive to the HSC field and JACIE's integral role in the process of implementing the Directive.

- Development of education materials (Work Package 3)
- Mechanisms for disseminating data and information (Work Package 6)
- Establishment and operation of training courses (Work Package 7)
- Creation and operation of networks and platforms (Work Package 9)
- Preparation of reports and publications (Deliverable 11)

The Information Packs distributed during the project have a particularly important role in ensuring that medical professionals outside of the existing JACIE network, as well as health authority officials throughout Member States, both old and new, are aware of the important of regulation in the field and served to highlight both the application of the EU Directive and the JACIE programme in this area.

The central training of JACIE inspectors and the employment of an exam ensure that there is a pool of well qualified inspectors in the field, trained in the same way and to the same depth. These JACIE inspectors in the future will go onto help implement the JACIE programme within the framework of the EU Directive and will be able to offer expertise and expertise to other competent authorities involved in regulating the HSC field.

The generation of progress reports via the online system provides a valuable tool for communicating with health authorities and official bodies at the EU level on the progress of implementation of standards in the HSC field. Unfortunately it was not possible to take advantage of this facility within the lifetime of the project, because the system was not functioning until December 2004 and the legacy data could not be input into the system until June 2005. The sort of report that can be easily generated by the system and be produced at either the national or global level is included as an appendix under WP 6.1. The extraction of this data from the system will also allow for it to be fed into the network of

EBMT and national registries to carry out future analysis of the impact of standards on transplant outcome, as well as assessment of the economic impact. Such data may be valuable in promoting standards in the future.

The extension of the network of JACIE National Representatives has allowed JACIE to target a wider audience that it was previously able to do. This is very important for harmonisation and ensuring that none of the new Member States are left behind in terms of their knowledge and understanding of the regulatory framework being put into operation.

Reports and publications, including active dialogue and presentations on the EU Directive and the JACIE programme at annual EBMT meetings has also ensured that the medical profession and the scientific community as a whole are aware of the importance of standards and accreditation in the HSC setting.

Monitoring, assessment and other evidence which forms the basis of this positive evaluation are:

- Sample copy of the Information Pack and distribution lists (WP 3.1)
- Inspector qualification criteria and exam (WP 7.1) / positive evaluation of the JACIE Inspector training course (WP 7.4)
- JACIE accreditation status report (WP 6.1)
- Press Book (WP 11.3)

Strengthening of central resources of the JACIE programme and extending and enhancing the effectiveness of the existing JACIE network

The extent to which the central resources of the JACIE programme have been strengthened have already been highlighted under objective 2 on implementation of JACIE. What needs to be added here is the great satisfaction of JACIE will the online system developed through the JACIE project. Although we were not able to reap the benefits of the system in the lifetime of the project, the amount of time and resources which went into developing the system is felt to be well worth is and a positive legacy for the future of the JACIE programme.

As detailed under Work Package 5 the JACIE Online system more than meets the initial specification and now enables the whole accreditation process from start to finish to be managed online. This represents a tremendous saving in terms of time and resources and keeps paperwork and costs to a minimum. It also enables JACIE to store very confidential data within a safe environment and provides a tremendous data resource for future reference. The fact that all of the countries currently participating in the JACIE programme (with the exception of Germany) are prepared to use the centralised system demonstrates acceptance of centralised management and will make this resource all the more valuable for ensuring comparability between the application of the JACIE standards and accreditation across Europe.

The system is currently being used effectively by centres, inspectors, the medical consultant and the JACIE administrator to manage all new accreditations. Unfortunately it was not possible to do a user survey of the system within the lifetime of the project and the JACIE Office has been too busy entering legacy data onto the system to carry out such testing post-project. However, the User Guide to JACIE Online, supplied as an appendix under WP 5.1 is proving an effective tool for new users and no difficulties in using the system have been reported to date.

The meetings organised by the JACIE Office with EBMT members in countries outside the previously existing network of JACIE national representatives (Work Package 9) and the supply of Information Packs (Work Package 3) to these members has ensured that they have been kept abreast of the JACIE project and of the EU regulatory developments. The appointment of 7 new JACIE national representatives is testimony to how seriously JACIE has been taken in some of the countries and it is particularly satisfying to see countries like Greece and Turkey move forward at great pace in the adoption of JACIE. The fact that countries like Estonia, Slovenia and the Slovakian Republic are now incorporate into the JACIE network and participate on the JACIE Board helps to get the smaller countries with lower resources on board and should help identify the sorts of issues which may be faced by other such countries in adapting to a culture of standards and quality management.

Establishment of equivalent JACIE training courses for medical professionals and inspectors across the Community and facilitating the exchange of experience and best practice between them

A very detailed overview of the activities under Work Package 7 and how they have contributed to the objectives were given in section 1 of this report and are therefore not repeated in this section. I would however conclude that the development and delivery of JACIE training courses and core curricula has been a success, as illustrated by the positive evaluation of the courses given and the ongoing application of the course materials and Kerteza trainers for future courses. It has been accepted that all JACIE inspectors must go through a training course and exam coordinated by JACIE to ensure that inspectors are qualified in the same way.

The extensive documentation (course materials, evaluations, etc.) presented as supporting documentation under Work Package 7, illustrate the level of work carried out on this activity during the "JACIE" project.

An area which proved more problematic to the project has the development of model materials. Whilst samples of documents and plans produced during the training courses were made available to course participants as reference documents, it was not possible to compile the final model materials until the end of the project when real documentation was available for review and the experience of the JACIE office was sufficient to distinguish the most valuable materials to include in the model materials pack. In this regard we are only very much at the beginning and a lot more work needs to be done to evaluate the materials and ensure that centres are given sufficient guidance and support on

the onset of preparing themselves for accreditation. Limited knowledge and lack of culture of quality management in the transplant setting, particularly in clinical practice have been identified as a weakness in centres participating in JACIE, as illustrated by the report on common difficulties and deficiencies prepared from the surveys completed post-inspection (surveys and report included under WP 10). More support from professional quality managers is therefore needed to continue to develop materials and provide consultancy support for facilities preparing for accreditation. A quality manages network is already in the process of being established and will help build on the sharing of best practice, which began through the "JACIE" project.

Contributing to the comparability of data across Member States by supporting the collection of compatible and comparative data

This was in many ways a more minor objective of the "JACIE" project, as it was appreciated this is a much more long-term objective and not something that was achievable with the initial 12 month timeframe of the project. The data available on JACIE online is highlighted in Work Package 6 (and supporting documents) and some thought and analysis was given to how JACIE online and the network of EBMT and national registries might contribute to the comparability of data across Member States by collecting comparable data (work package 11.2, page 37 and 38 of the report) . Although a report on this point was not finally produced, it is something that has been discussed between the EBMT registry and JACIE Office and the possibilities of extracting data from JACIE online to feed into the EBMT registry network are feasible and something that will be considered seriously by JACIE and the EBMT.

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