Final Report
2004-2007 Period

EUROPEAN QUALITY SYSTEM FOR TISSUE BANKING PROJECT

Agreement Number 2003209
# SANCO-EQSTB Project
## Final Report
### 2004-2007

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INTRODUCTION

The main objective of this project is to analyse throughout four different working areas the factors that may influence the final tissue quality and security for its transplantation providing finally a greater benefit to recipients. The project aims to develop the method to ensure standards of quality and safety in relation to tissue banking activities demanded by the future implementation of the European Directive on Tissue practices approved in March 2004.

This project is divided in 4 main working groups. The objectives of each one are focused in a specific area:

1. **Standards Working Group:** Perform a comparative analysis of the different standards followed in the participating countries to detect the tissue banking quality and safety key points. Define the number of standards or guides followed and quantify the differences and similarities among them. Study the rate of implementation of the European Directives on Tissues and Cells. Develop the Guide of Recommendations defining the quality and safety key points on tissue banking.

2. **Registry Working Group:** Define the common terminology and variables of tissue banking in order to create the common Registry to observe the possibility of exchanging tissues between tissue establishments throughout different European countries. Define a prototype of a Registry Network Database for the entire tissue banking process: donation, processing, preservation, traceability, clinical application and adverse reactions after transplantation. Make available the database on the Internet with a Search Function and validate the Registry prototype through a pilot data charge.

3. **Education Working Group:** To design and validate a specialised training model among tissue bank personnel that afterwards can become the approved education recommended by the European Union members. This model will be based on the banking personnel’s profile and the knowledge and training needs detected. This model aims to be afterwards a method of qualifying personnel and finally certify
their knowledge in a European Certification.

4. Auditing Working Group: Design a European Auditing Model of tissue establishments based on EU Directives on tissues and cells, and on the tissue banking quality and safety key points, the common nomenclature data registry system and the specialised training model. Perform 4 pilot audits using the audit model to improve and validate the model. Develop a transferability report describing the applicability of the model at European level.
This final report includes the detailed explanation of all the activities that have been carried out during the last working period of the EQSTB project (May 2006- May 2007). Being this document the last report of the project, we have felt it necessary to also include a short outline of the activities carried out during the two previous years. This will make it easier to relate the intermediate outputs of the project and the final results.

The report is divided in five main items:

1. Promoter’s activities execution
2. Standards working group activities execution
3. Registry working group activities execution
4. Education working group activities execution
5. Auditing working group activities execution

Each one is further subdivided in four other items:

1. **Organisation**: describes the organization or organizations that participated in the activities that will be later described
2. **Objectives**: explains the objectives that were set for this working period and the timings. It also describes which tasks depended on the results obtained by other working groups.
3. **Activities developed**: details the activities carried out and what was the participation of the partners. It also relates the results obtained to the project calendar and the project objectives. Furthermore, this point explains the tools that were used to obtain those results and the different factors that have influenced in these results. Finally it shows the conclusions and analyses any deviation of the results expected. Incidences occurred during this period, if any, are also mentioned in the point.
4. **Future activities**: describes the activities that will be taking place after the project finalizes and the foreseen calendar and partners in charge of their execution.
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2.1 Organisation

Hospital Clínic i Provincial de Barcelona, Spain.

Manager: Dr. Martí Manyalich.
Coordinator: Dr. Aurora Navarro.

2.2 Introduction

Europe’s tissue banking activity background is very diverse. The origin and consequently the organisation of the different banks among different countries is greatly unlike. Security and safety from donor selection criteria until tissue suitability for its transplantation varies depending on the tissue bank control over the whole process. Traditionally some banks consider donor selection criteria the critical step to avoid infectious transmission throughout tissue transplantation even when final sterilisation is performed. Usually these tissue banks have a strong control over donor evaluation process.

The banks that work independently from procurement organisation usually receive the tissue without complete donor information with blood samples for serologies, so a final sterilisation process is considered mandatory.

Independently of tissue bank development and control over the process, it has been proved that quality control is necessary throughout the whole process because of the risk of infectious disease transmission.

The main objective of this project is to analyse throughout different working areas the factors that may influence the final tissue quality and security for its transplantation providing finally a greater benefit to recipients. The project aims to develop the method to ensure standards of quality and safety in relation to tissue banking activities demanded by the future European Directive.

The project can be summarised by the following four specific objectives, which are tasks to be developed by the four different working groups respectively:
1. **Standards Working Group:** Perform a comparative analysis of the different standards followed in the participating countries to detect the tissue banking quality and safety key points. Define the number of standards or guides followed and quantify the differences and similarities among them. Study the rate of implementation of the European Directives on Tissues and Cells. Develop the Guide of Recommendations defining the quality and safety key points on tissue banking.

2. **Registry Working Group:** Define the common terminology and variables of tissue banking in order to create the common Registry to observe the possibility of exchanging tissues between tissue establishments throughout different European countries. Define a prototype of a Registry Network Database for the entire tissue banking process: donation, processing, preservation, traceability, clinical application and adverse reactions after transplantation. Make available the database on the Internet with a Search Function and validate the Registry prototype through a pilot data charge.

3. **Education Working Group:** To design and validate a specialised training model among tissue bank personnel that afterwards can become the approved education recommended by the European Union members. This model will be based on the banking personnel’s profile and the knowledge and training needs detected. This model aims to be afterwards a method of qualifying personnel and finally certify their knowledge in a European Certification.

4. **Auditing Working Group:** Design a European Auditing Model of tissue establishments based on EU Directives on tissues and cells, and on the tissue banking quality and safety key points, the common nomenclature data registry system and the specialised training model. Perform 4 pilot audits using the audit model to improve and validate the model. Develop a transferability report describing the applicability of the model at European level.
2.3 Objectives

The main objectives of the EQSTB project promoter were:

- Organization of the I Working Meeting in Barcelona: constitution of the project working groups, the follow up committee. Definition of the Communication tools and operative working plan of the project. December 2004 ✓
- Construction of the On Line Communication Platform: private working space (BSCW), mailing list and public website. December 2004 ✓
- Supporting the different working groups. Organizing the tasks and watching for the fulfilment of the project objectives. July 2004-May 2007 ✓
- Organization of the II Working Meeting in Bologna: presentation of results and approval of the working plan for the next stage. November 2005 ✓
- I Meeting of the Follow up Committee: analyses of the objectives achieved until that moment. November 2005 ✓
- Internal Budget control: analyses of the expenditure made at the project mid-stage so as to control possible deviations. November 2005 ✓
- Organization of the final Consortium Meeting. Discussion and debate of results, its transferability and application. February 2007 ✓
- Elaboration of the project technical and financial annual reports: 1st report (September 2005), 2nd interim report (July 2006) and final interim report (May 2007) ✓
- Distribution of the first (November 2004) and second EC payments on time to the project partners. December 2006 ✓
- Dissemination of the project results: publications of articles, assistance to congresses and distribution of project publications. March 2007-March 2008
The specific objectives for the final period of the Promoter organization were to continue with the responsibility of coordinating the working groups’ tasks and watching for the correct development of the project both technically and financially.

The description of the activities developed by the promoter is divided in four points:

- General Management Issues
- Technical Management Issues
- Financial Management Issues
- Communication Tools Updates
2.4 Activities developed

2.4.1 General Management Issues

This point is further subdivided into:

− 2.4.1 General management issues: deals with the tasks that the project has undertaken during the project such as informing and updating the EC about the project, organizing deliverables, arranging project meetings,

− 2.4.2 Partner issues: details any incident related to the partners of the project.

− 2.4.3 Technical management issues: describes the work done by each working group. Other activities of technical nature such as the project external audit, the dissemination strategy, the follow up committee meetings, etc are also described there.

− 2.4.4 Financial management issues: financial matters such as yearly financial justifications, budget modifications and other economic incidents are explained in this section.

− 2.4.5 Communication tools: describes the three communication tools, gives updates and explains incidences.

I. Project Working Meetings

The duration of the project was three years. The Promoter planned one meeting per year, therefore three meetings were scheduled. The purpose was to gather all partners in order to share results and work face to face on the project.

The meetings were planned as follows:

− Barcelona (July, 2004)
− Rome (November, 2005)
− Barcelona (May, 2007)

The first project meeting dates were postponed from July 2004 to December 2004. Summer time made it difficult to find a hotel with availability for all the project
partners. Also partners agreed that they needed to receive the 1st EC payment in order to cover the travel expenses of the meeting.

This first meeting was very useful so that all partners could know each other, and groups could plan their work together. The Follow up Committee was also constituted in this meeting.

The second project meeting venue was changed from Rome to Bologna. November 2005 marked the central point of the project therefore it was important that the consortium could meet again and to be able to plan the work schedule for the final stage of the project.

In October 2006 the project promoter started to organize the project final meeting. As it was the last time that the consortium would meet it was important that the meeting was announced through e-mail with enough time to assure the attendance of everyone. All project partners and the EC were invited to assist this meeting. In spite of that, four organizations were not able to send their representative to the meeting.

The dates chosen for the final meeting were February 15th and 16th. The meeting was meant to take place in Barcelona but due to an important fair there was no room enough for all the partners in the city. Finally it was decided that the meeting would be held at Castelldefels, a nearby town.

Hotel accommodation and subsistence was organized by the promoter so that this met the money requirements of the EC. An e-mail with all the details of the meeting and the working agenda was sent to everyone.

Each working group was asked to prepare a 10 min presentation to be displayed at the meeting. This was meant to show the results obtained from May 2006 until February 2007. A personalised e-mail explaining the importance of the meeting presentations was sent to each group. Since the meeting marked the ending of the project there was a lot of work to be explained and conclusions to be drawn. Additionally, they were also asked to attend the meeting with a list of specific tasks done that needed to be discussed and agreed by all.

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1 ANNEX A Final Meeting Announcement
2 ANNEX B Final Meeting Details and Working Agenda
3 ANNEX C Working Groups’ e-mail
During the first day of the meeting the groups’ presentations were displayed. This allowed groups to share their results with the rest of partners. After each presentation partners were given time to make questions about the results presented. Suggestions from other partners were also welcomed. Final arrangements and work lines were agreed by all partners.

During the second day the Guide of Recommendations and the Guide for Tissue Establishment Auditing were presented to the partners. Draft copies were distributed among partners so that they could have a look while these were presented. This allowed that the rest of partners could give their opinion on both future publications.

The dissemination strategy of the project results was also discussed and agreed during the meeting. Partners agreed in which local and international meetings the results could be presented. Also the way how the results should be presented was discussed (i.e. round tables, morning sessions, etc).

The meeting was also good for the follow-up committee who had the chance to make an analysis on the results obtained during the working period. The meeting ended with the conclusions from the working groups and the promoter.

After the meeting partners received the meeting minutes by e-mail. All meeting presentations were uploaded in the BSCW so that everyone could review them.

**Partner Issues**

In October 2005, the Etablissement Français des Greffes (belonging to Standards’ Working Group) communicated the project promoter the change of name of its organisation. The partner’s new name would be *Agence de la Biomédecine* instead of *Etablissement Français des Greffes*.

During the same period, the Netherlands Bone Bank Foundation (belonging to Education Working Group) announced their resignation to participate in the project. Since the person in charge had left the organization and they had a shortage of qualified personnel, they had no other solution but to drop their participation. The

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4 ANNEX D Final Meeting Presentations  
5 ANNEX E Meeting Conclusions Presentations  
6 ANNEX F Meeting Minutes
technical and financial responsibility was passed to Transplant Services Foundation (leader of Audit Working Group).

In both cases the promoter contacted the Project Officer in order to inform about these incidents. The changes that implied both matters were first approved by the partners and then by the European Commission.

Finally, no important partner issues were registered during the final working period.
2.4.2 Technical Management issues

- Standards
  The involvement of this group has been continuous throughout the three years of the project. During the first year the standards and protocols used by the partners of the project were studied. The second year was aimed at developing the *Guide of Recommendations*. This is one of the two publications of the project. It is based on the quality and safety key points for tissue donation, procurement, processing, allocation and transplantation.

  During this final working period the standards working group studied the rate of implementation of EU Directives in the partner organizations. They also continued to develop a *Guide of Recommendations* that met the EC requests. Also the suggestions made by the project partners and the project technical auditors were adopted.

  These points are dealt in detail in the Standards’ Working Group chapter. (see page 39)

- Registry
  The Registry Working Group tasks during the first period was centred in obtaining the transplant and donation variables needed to create the future Registry. During the second working period a registry network database was developed. Partners could enter in this pilot version and give their opinion. The EC was also invited to access the Database during this trial period.

  In the final project period a definitive version of the Registry was uploaded and the four chosen tissue banks introduced data in it. The data charge resulted in some more changes aimed at improving the registry.

  For further information regarding the activities of this group please see chapter 53.
- **Education**
  
  During the first year of the project, the Education Working group studied the knowledge and the needs of tissue bank workers. During the following year a training model was designed and presented in the Interim Meeting.

  Both parts of the training were implemented later during the same year. Attendants' results and opinion on the course was analysed and conclusions were drawn. The training was adapted according to the conclusions and a definitive model was presented in the final working period.

  In February the working group leader attended together with the project promoter to the Competent Authorities Meeting in order to present the training they had designed. For detailed information, please refer to the education chapter (page 72)

- **Auditing**
  
  The tasks of this group were dependent on the results of the three other groups; this made their activity to start later. During the first working period a draft of the auditing model was defined through the study of different quality models.

  The model was developed in detail during the second working period taking into account the results obtained up to that time by the other three working group. During the Interim Meeting the preliminary auditing model was presented.

  During the final working period, the model was implemented by auditing 4 Tissue Banks. Also, the Guide for Auditing Tissue Establishments has been developed including the information from the other three working groups and the data from the EU Directives on tissues and cells.

- **European Commission Letters**
  
  After sending the 2nd Interim Report in July, the Commission wrote the promoter in September. In the letter\(^7\) additional information on certain of the results that had been obtained during the 2\(^{nd}\) working period was requested. The request for additional information was based in various different points of the four working groups.

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\(^7\) ANNEX G European Commission 1\(^{st}\) letter
The promoter’s response was immediate. Partners were informed about the incident and their collaboration was demanded. The promoter wrote each working group an e-mail where the Commissions’ requests were dealt individually. Partners started working to solve the Commission’s questions. A few days later a report\(^8\) with all the information requested was submitted to the EC.

After receiving the report the Commission sent another letter\(^9\) in October with more enquiries. Apparently some points still remained unclear. An answer was provided through telephone.

- **Follow up Committee**
  
  Constituted in the 1\(^{st}\) working meeting, its aim was to watch over the correct performance of the project. It is composed by each working package leader as well as the project promoter.

  During the 2\(^{nd}\) meeting the Follow up Committee met for the first time and evaluated the project progress. The promoter wanted to control any possible deviation in what had been planned both technically and financially. The analyses of the present situation would allow detecting possible problems and to plan a strategy to solve them. Instructions for interim budget control were also given to partners.

  During the final meeting, the committee had the opportunity to meet again and make a final evaluation of the project. It was concluded that the project’s evolution had been as planned. Despite a few small variations in the planned timings, the objectives that were planned had been finally achieved.

- **External Audit**
  
  A final project evaluation was planned for the end of the project. The evaluation had two parts: a technical one and a financial one. Both were carried out by external auditors.

  For the **technical audit**, two experienced tissue bank professionals were hired: Scott Brubaker (AATB Chief Policy Officer) and Deirdre Fehily (Tissues and Cells Lead Inspector and external consultant of the Italian National Transplant Centre). Both

\(^{8}\) ANNEX H Project Promoter Answer to 1\(^{st}\) letter

\(^{9}\) ANNEX I European Commission 2\(^{nd}\) letter
visited the Project promoter on different dates in order to carry out the audit independently.

The idea behind hiring two technical auditors was that the project results could be analysed from both the American and the European perspective. The objectives of the audit were as follows:

1. To analyse the achievement of the objectives that had been set.
2. To detect any deviation from the initial objectives. To investigate the cause of possible deviations and to see if they were justified.
3. To check the quality of the results obtained by the project.
4. To confirm that the timings had been fulfilled. If the work plan presented at the management plans had been strictly followed.
5. To verify the effectiveness of the consortium management and the partner participation.
6. To analyse the project relevance, sustainability and impact.

Both auditors were given the same information to carry out the analyses of the project results. The documentation that they had to review was the following:

- Project call for proposals
- 1st Interim report and 1st management plan (2005)
- Letters from EC
- Guide of Recommendations
- Guide for Auditing Tissue Establishments

The work plan was to audit the Promoter during a whole day. First, the promoter presented the project to the auditor; previously the auditor had received all the information above mentioned electronically. The auditor made questions to the promoter in order to solve any unclear point. Once the audit was finished the auditor
examined the documentation given and the notes taken during the audit. An audit report\textsuperscript{10} was written after each audit.

Secondly, a \textbf{financial audit} was also carried out, in May 2007. Once all the project tasks had finished no more expenditure was left to be done. Therefore, the financial audit of the Project Promoter could take place. An external team (Busquet Economistes i Auditors) was also hired for that purpose.

The objectives of the financial audit were:

- To certify that the financial documents submitted to the Commission comply with the financial provisions of the agreement.
- To certify that the costs declared are the actual costs and that all receipts have been declared.

The documentation that the auditor reviewed was the following:

- Project Proposal
- EC agreement n. 2003209
- 1\textsuperscript{st} Financial Justification (Promoter)
- 2\textsuperscript{nd} Financial Justification (Promoter)
- 3\textsuperscript{rd} Financial Justification (Promoter)
- Timesheets and payslips (Promoter)
- Invoices (Promoter)

The auditor team was made up of 1 person. The work plan of the team was to audit the Project Promoter during 1 day. As a result an audit report\textsuperscript{11} was written.

\begin{itemize}
  \item \textbf{Dissemination}
  A dissemination strategy was planned and approved during the final working meeting.\textsuperscript{12} The strategy was based on four types of actions:
\end{itemize}

\textsuperscript{10} ANNEX J Technical audit reports by Scott Brubaker and Deirdre Fehily.
\textsuperscript{11} Please see the Financial Audit Report documentation.
\textsuperscript{12} ANNEX D9 Final Meeting Dissemination Strategy Presentation
1. Distribution of the two project publications: *Guide of Recommendations* and *Guide for Tissue Establishment auditing*

2. Attendance to international and local meetings

3. Publication of articles in scientific journals

4. Project Website

These actions were thought to take place from March 2007 until December 2007. Even though the project finished in May, partners compromised to continue disseminating the project results at those meetings where they had already planned to attend.

1. **Project Publications:**

The *Guide of Recommendations* has been published in colour and in A4 format. It presents the information in a very visual way (using flowcharts, tables, forms). Its structure and design make it a quick consult tool.

The *Guide of Tissue Establishment Auditing* has been printed in two colours and in a smaller format. The idea was to make it a convenient and handy consult tool for tissue bank professionals. Its design allows workers to have it open on their desks while working. This is why it has been bound with double loop wire and in a small format.

The distribution of the two project publications was made according to the table that follows:
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<th>Guide of Recommendations 2000</th>
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<td>United Kingdom</td>
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<td>Transplant Services Foundation</td>
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| TOTAL            | 2062                              | 2000                   |                               |                  |

Each project partners will receive 55 copies of both publications. The exceptions are the 3 national organisations participating in the project (ONT, ABM...
and CNT), these will receive 150 copies of each. The rest of publications will be sent to Tissue Banking Organisations such as AATB, BATB and EATB. The remaining copies of the Guide for Tissue Establishment Auditing will be stored by the promoter. They will be distributed as future congresses take place.

2. Attendance to meetings:

All project partners are involved in this task (not only the promoter or the working groups’ leaders). Before the final meeting, partners were passed a table that had to fill in with the congresses where they will be attending both locally and internationally. The table was divided in 10 months. The dissemination period started when the final results and conclusions of the meeting were presented at the last meeting in February. Partners were informed on how to proceed and it was agreed that March 2007 was the starting date for the dissemination actions (project and project results; the guides were not yet finalised in those dates). these would be held. The list was thought for the year 2007; however some partners even added meetings for the start of the year 2008.

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<thead>
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</table>

This table allowed the promoter to plan each dissemination act. Using the partners’ tables, a general dissemination table was built (see next page).
### International Meetings 2007-2008

<table>
<thead>
<tr>
<th>Date</th>
<th>Place</th>
<th>Meeting</th>
<th>Action</th>
<th>Attendees</th>
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</thead>
<tbody>
<tr>
<td>Apr 25th – 28th</td>
<td>Lyon, France</td>
<td>EBMT</td>
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<td>Francesca Vespasiano</td>
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<td>Caterina Delvecchio</td>
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<tr>
<td>Apr 26th</td>
<td>Nottingham, UK</td>
<td>BATB 26th-28th</td>
<td>round table</td>
<td>Stefan Poniatowski</td>
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<td>Esteve Trias</td>
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<td>Clara Fernández</td>
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<tr>
<td>May 5th-9th</td>
<td>St. Francisco, USA</td>
<td>American Transplantation Congress 2007</td>
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<td>Martí Manyalich</td>
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<tr>
<td>Jun 14th-16th</td>
<td>Vilnius, Lithuania</td>
<td>6th International Congress of Baltic Medico Legal Association</td>
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<td>Grigory Vabels</td>
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<tr>
<td>Sep 25th-27th</td>
<td>Boston, Massachusetts</td>
<td>AATB 11th Annual Spring Meeting</td>
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<td>Aurora Navarro</td>
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<td>Martí Manyalich</td>
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<tr>
<td>Sep 29th-30th</td>
<td>Prague, Czech Republic</td>
<td>ETCO 2007 Congress</td>
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<td>Martí Manyalich</td>
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<td>30th-October 3rd</td>
<td>ESOT 2007 Congress</td>
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<td>Oct 18th – 20th</td>
<td>Budapest, Hungary</td>
<td>16th International Conference of the EATB</td>
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<td>Francesca Arrivi</td>
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<td>Claudia Ferraro</td>
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<td>Aurora Navarro</td>
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<tr>
<td>Nov 11th-14th</td>
<td>Philadelphia, USA</td>
<td>Organ Donation Congress (ISODP)</td>
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<td>Martí Manyalich</td>
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<td>Dec 1st-4th</td>
<td>Pattaya, Thailand</td>
<td>10th Congress of Asian Society of Transplantation</td>
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<td>Martí Manyalich</td>
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<td>Jan</td>
<td>Munich, Germany</td>
<td>XX Annual EEBA Meeting</td>
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<td>Esteve Trias</td>
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</table>
During the final meeting it was agreed that:

- A presentation\(^{13}\) containing general information on the project and the working groups would be made. This would be used by the Project Promoter to disseminate the project results at meetings.
- Each working group would make a presentation\(^{14}\). This would be used by partners in order to disseminate the results of their own group at meetings.

3. **Publication of articles:**

Regarding the publication of articles, it was agreed that these were the possible dissemination tasks:

- The project promoter would write a general article with the overall results of the project. This would be submitted to several medical journals.
- Each working group would write an article with their own results. These would be submitted to several medical journals.

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\(^{13}\) ANNEX K Project Promoter presentation for dissemination events

\(^{14}\) ANNEX L Working groups presentations for dissemination events
The possible journals/magazines in which the articles might be published are detailed below:

<table>
<thead>
<tr>
<th>Date</th>
<th>Publication name</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Tissues and Cells</td>
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<td></td>
<td>American Journal of Transplantation. Official Journal of the AST/ASTS</td>
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<td></td>
<td>Cell and Tissue Banking</td>
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<td>Cell and Tissue Research</td>
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<td>Cells Tissues Organs</td>
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<td>Progress in transplantation</td>
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<td>Tissue Engineering</td>
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<td>Tissues and Cells</td>
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<td></td>
<td>Transplant Int</td>
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<td>Transplantation proceedings</td>
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</tbody>
</table>
2.4.3 Financial Management issues

During the two first working years there were some financial adjustments. These were explained thoroughly in the two past Commission Reports:

- Dropping of a project partner. Netherlands Bone Bank Foundation technical and financial responsibility was passed to Transplant Service Foundation.
- Location change of the face-to-face training (Coruña instead of Barcelona). This change brought along another change in the budget. The entity in charge of coordinating the face-to-face course (ONT) requested to have at its disposal a budget item to be able to administer directly the trips of the professors that gave classes.
- an internal settlement has been made on the Miscellaneous item since it was considered that the subcontracting of the "Technical development of a data base for the Registry" was best gathered in Miscellaneous Services-Subcontracting instead of in Miscellaneous Services-Other Costs.

In this final working period there were three budget adjustments. These were caused by the following situations:

1. Lack of Travel and subsistence budget for Working Group 4 Audits.
2. Lack of budget for the Correction of the two publications of the project.
3. Lack of budget for the Postage and packing of the two publications of the project.

The project officer was informed by mail\(^{15}\) of these and a possible solution was presented. In the three cases there were expenses that had not been foreseen for various reasons. These expenses were necessary therefore a budget adjustment had to be done in order to cover them. The first problem was solved by moving part

\(^{15}\) ANNEX M Budget adjustments letter
of the staff budget to travel and subsistence (according to article I.3.5). The second and third problems were solved by using some of the information budget.

- **Budget justification**

  In total there have been three budget justifications during the project:
  - 1\(^{st}\) Budget justification (May 2005)
  - Internal Budget justification (November 2005)
  - 2\(^{nd}\) Budget justification (May 2006)
  - Final Budget justification (May 2007)

  The procedure of each justification was the same. The promoter sent an e-mail with instructions on how they had to fill in the justification forms. Two kinds of forms had to be filled, one was the *Timesheet form* where partners had to state the days worked for the project and its cost. The second form was the *Annual Justification form*. In this latter partners had to state the amounts spent in personnel, travel and subsistence, etc. If they had doubts on how they had to proceed these were solved. All the partners’ justifications were checked and sent to the EC.

  In November 2005 there was an internal justification carried out by the promoter that was not sent to the EC. The aim of it was to allow the promoter to verify if there was any deviation of the budget and in case of deviation to apply corrective measures. Later in May 2006 the year justification was done.

  In May 2007, before the project ending, the promoter proceeded to carry the final budget justification. As happened with the other justifications, an e-mail \(^{16}\) with instructions regarding the budget control and how the justification forms had to be filled was sent. The importance of this and how partners had to proceed had been already explained during the final meeting. A power point with instructions on how to fill the budget control forms was created (See annex N).

\(^{16}\) ANNEX N Financial justification e-mail with justification forms.
2.4.4 Communication Tools Updates

The promoter role consisted in giving assistance to the users providing useful communication tools and make possible contact among partners. These tools were the following:

1. Official Project’s Website
2. Distribution List
3. BSCW Private on-line platform

1. Project’s official Website

The project’s official website was part of the Communication Platform. Its access was open and it contained general information on the project. It was created in December 2004 and since then it experimented modifications in its contents and menus.
It was built using *javascript*, *html* and *css* type sheets. It was designed so that it could be accessed from any Internet navigator. It charged quickly and it was easy to modify so that it could perfectly adapt to the needs of the Project. The idea was to have a useful tool both for people outside the project and for people in the project. It contained information on donation and tissue banking events as well as links to important websites on this subject.

The list of sections of the website was the following:

- **Home**: has the project statement.
- **Who are we?**: It contains a full explanation of the promoter, the aim of the project and the involvement of all the partners. There are also the contact data of each partner organisation including the name of the organisation project leader, address, e-mail address, and phone and fax numbers.
- **Overseas view**: The work distribution among partners is shown in this section.
- **Project focuses to**: This section informs about the project feasibility according to the European Work Plan 2003 – Health Threats – Tissues and Cells.
- **Project description**: Project summary that includes the four main activities to be developed by the four working groups.
- **Events**: has a table with the oncoming meeting in the donation and tissue banking world.
- **Documentation**: Once the deliverables have been finished, they will be available in this section.
- **Links**: Partner organisations were asked to include information about their organisation web site address obtaining a list of interesting links about the organisations involved but also about some external organisations, societies…
- **Project Meetings**: This section allows announcing the planned events related to the project, considering the specific dates and places.
- **Registry**: is linked to the musculoskeletal data base developed by working group 2.
- **Education**: contains information on both parts of the training (dates, programme, attendants).
- **Auditing**: contains the objectives and results of the WG4, and the Guide for Auditing Tissue Establishments
- **Highlights**: contains a quick access to the mail list, the archives of the mail list, the BSCW and the virtual course.
- **Standards**: contains information on the objective and results of the WG1, and the Guide of Recommendations

During the first two working periods the webpage improved gradually. As the project activity increased new sections were added. These were updated regularly with new information. Each time changes were done in the website, partners were informed about that. No incidences were registered in the service.

In this last working period the project’s official website has suffered the following changes:

- Translation into French and German. At the beginning the webpage was only in English, during the 2nd project meeting it was decided that it would be translated into two other languages. These languages were agreed by all (August 2006)
- Change of the website’s address. The idea was to make the access to it easier and to have an address that could be quickly related to the project. The new address mentions the name of the EC programme and the name of the project as well as the promoter’s name. All project partners were informed of this change through e-mail in April 2007

  The chosen address was:

  http://sanco-eqstb.hospitalclinic.org/sanco/index.html

  instead of:

1. Addition of more information:
   - Events Section: the list of events related with donation and tissue banking has been regularly updated.
   - Documentation Section: the face to face training presentations were uploaded there. They are protected so that they cannot be printed or modified.
   - Links Section: one new link has been added in the section of partners’ websites.
   - Project Meetings Section: the final meeting dates and pictures have been added.

2. Creation of new sections:
   - Dissemination Section: contains information on the EQSTB dissemination events. The section is divided into International Events and Local Events. International Events contains a list with of the events with the dates, and the partners that will be attending. The Local events section is further divided into the 12 countries of the consortium. In it there is the list of the local events where partners will be attending to disseminate the project results.

There have been no incidences during this period a part from the change of place of the server. This interrupted the service for a few hours. Later in January the server was moved again and the service had to stop for an hour. Partners were informed about the two incidences by e-mail.
2. Distribution list:

It is a service provided by Red Iris. It allows internal communication among the different Project participants through e-mail. The promoter’s job has been that of configuring the characteristics of the list, adding new users, removing old ones and giving assistance to the list members. The mail list has been configured with those options that were more adequate to the project needs. It has been modified on users’ request and according to the characteristics of the system. For instance the list was configured so that members could distribute .zip files.

Whenever partners want to communicate with the other partners or share a document, they just have to write to the following address SANCO@LISTSERV.REDIRIS.ES in an e-mail so that e-mail reaches the rest of partners. This tool saved time and allowed to have a registry of old messages (stored in the Rediris webpage and in folders, months by month). Access to the messages archive is only possible for project participants.

During the first two years of the project the SANCO-EQSTB mail list has continued to be a very important tool for communicating with the partners.
Administrative tasks have been carried out like those of adding and removing members from the list and solving doubts on the use of this tool.

A total of 106 e-mails were sent to the list from January 2005 until May 2007. The average number of e-mails per month was of 3. The total number of users of the list was 24. The members by countries were the following:

- Finland 1
- Germany 2
- Italy 6
- Netherlands 2
- Poland 3
- Romania 1
- Slovakia 1
- Spain 6
- Others (.com, .org, …) 2

The incidences detected during these three years have not been very significant. When the list was set up, two users did not know how the list worked and did not sent the confirmation mail to the list consequently their access expired. Later, new e-mails to subscribe to the list were sent to them and the problem was solved. There were also two cases where the e-mail addresses of the subscribers were wrong and they did not receive the subscribing messages. Their addresses were corrected and the problem was solved.
3. **BSCW Private on-line platform:**

The idea behind this tool was to have a common working space where only partners could access. This application not only allows the sharing of all kind of files but also allows making a follow up of the development of the files that is uploaded by the different partners. It also allows structuring information into folders, opening discussion forums about uploaded documents, sharing an agenda, etc.

As mentioned before, BSCW was a tool for collaborative work. It allowed to have structured work spaces where files could be shared, to generate discussions on these archives, to keep a shared agenda of events, to have a list of group members or a follow up of new materials creation.

There are a total of 33 users in the BSCW, and a total of 39 shared documents.

Like it happened with the mailing list, administrative tasks were carried out as well as technical assistance tasks.

The on line working space contains the following information folders:
− **General Information:** contains the manual for the financial and administrative management, the call for proposals document and a file that partners can use in order to justify the worked hours.

− **Help Desk:** contains two manuals of instructions so that partners could have a general approach to the BSCW system and to the use of discussion forums. These were included in the past Interim Report Annexes. The first manual gave general information on the BSCW. The second manual was specially designed so that partners could learn how to use the discussion forum option of the BSCW.

− **Working Group 1-Standards:** contains a word document with a questionnaire on regulations and standards that was passed by this group. During the final working period the drafts of the Guide were uploaded there so that partners could check them. Now the final version of the Guide of Recommendations is uploaded there.

− **Working Group 2-Registry:** contains two power points. One is the power point for the first meeting and the other is a manual with instructions on how the registry works.

− **Working Group 3-Education:** contains one power point that was displayed during the first meeting. It also contains a knowledge questionnaire for TB workers. Finally it has a registration form for the EQSTB training and aid document.

− **Working Group 4-Auditing:** contains one power point that was displayed during the Barcelona meeting. During the final working period the drafts of the Guide were uploaded there so that partners could check them. Now it has the final version of this guide.

− **Library:** contains the Directive 2004 23 EC

− **Meetings:** contains all the presentations of the 3 working meeting of the project.

− **Dissemination:** displays the presentations used for dissemination purposes.

The incidences have been, in general, slight: doubts on how the BSCW works, user configuration, password loss and subsequent distribution of a new one.
4. **Server administration services for the Registry:**

It consisted in giving assistance to Working Group 2. The participants of the group built a web application that allowed registering tissues in a database for its future exploitation. The promoter’s task was that of server administration. The application was installed in the project server and was made accessible to the rest of participants. This application was built using .ASP language and an Access database. The details of the tasks carried out by the promoter were:

- Identifying which is the best configuration for a proper performance of the application.
- Starting and configuring the IIS server (Internet Information Service de Microsoft) for the application.
- Installing and configuring the application so that it can be accessible to users.

Some incidences were detected when updating the application due to licenses of access. These were solved immediately. On the other hand, it was detected that the current configuration made the database unsafe since it could be downloaded through the web. The promoter did not finally migrated it to a safer database management system. The reasons for these are:

- The data inserted is very little. Experts do not recommend migrating it as long as we do not manage a high quantity of data (ie: more than 100 000 entries).
- The number of users is low too. More than 10 users, allowed to access at the same time the registry, would be a risk. This is not the case.
- The system has worked perfectly so far.
- The migration task would have implied and extra cost for the project.
2.5 Future activities

After the Project’s ending, the promoter will continue with the dissemination task. This includes the presentation of project results at the different congresses that the promoter has planned to attend until March 2008. Also during this period the results of the project will appear in different medical publications.
<table>
<thead>
<tr>
<th>Stages of project/Deliverables</th>
<th>Month 1</th>
<th>Month 2</th>
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<th>Month 34</th>
<th>Month 35</th>
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<td>0. 1. Starting up the project: constitution of up Committee and 4 working groups</td>
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<td>0.2. First Meeting at Barcelona</td>
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<td>0.3. Technical development of Project Platform communication</td>
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<td>1.1. Comparative analyses of different standards used in the different countries of the consortium.</td>
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<td>1.2. Study about rate of implementation of standards and diagnosis about capabilities in order to the accomplishment of future Directive. Report</td>
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<td>1.3. Recommendation of standards operating procedures based on tissue bank reality. Guide Recommendations</td>
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<td>2.1. Proposal of common coding system that vocabulary among tissue banks</td>
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<td>2.2. Registry Network Database defined with a group of standardized variables for all the tissue bank</td>
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<td>2.3. Searching System developed in order to the localisation and tissue exchange among banks</td>
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<td>3.1. Describe and analyse tissue banking personnel’s profiles for medical director, processing technician, quality assurance, procurement technician. Professional profiles and job description cards obtained</td>
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<td>3.2. Measurement of personnel’s specialised knowledge of partners. Analyse of training needs</td>
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<td>3.3. Definition of a model of training: contents program, methodology, specialised blocks depending on profiles.</td>
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<td>3.4. Validation of the training model. Pilot experience with 28 people of all countries.</td>
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<td>3.5. Evaluation of pilot experience and Final adaptations of training program</td>
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<td>4.1. Definition of Audit Model: final production of standards and recommendations; registry database; auditing of personnel qualified.</td>
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<td>4.2. To perform a volunteer pilot audit of the Model at least on 4 partners (tissue banks). Pilot Certified audit.</td>
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<td>4.3. Analyse transferability and application of the auditing model at European Union level</td>
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<td>5. Second working Meeting at Bologna</td>
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<td>7. Final Meeting. Distribution of Results and Publication of the Model.</td>
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<td>8. Final Project Evaluation (External and Internal)</td>
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WORKING GROUP 1 ACTIVITIES EXECUTION – STANDARDS

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     - Diagnosis of the capability to accomplish European Directives
     - Definition of the Quality and Safety Key Points
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     - Rate of Implementation of EU Directives
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4. Future Activities
1. Introduction to WG1.

Group members:
Assoc. Prof. Jan Koller, M.D., PhD, Central Tissue Bank Bratislava, Slovakia
chairman
Bernard Loty, M.D., Agence de Biomédecine, Paris, France, co-chairman
Olivier Cornu M.D. Bone Bank Brussels, Belgium
Grigory Vabels, M.D., State Forensic Medicine Centre, Latvia

Tasks:
The main objective of Working Group 1 was to develop a Guide of Recommendations for tissue banking activities describing the Quality and Safety Key Points that are considered fundamental for the adequate functioning of a tissue establishment, guaranteeing the highest level of quality and safety of tissue grafts for transplant.
To achieve this, the current situation in Europe was studied. A comparative analysis of the different standards or guides followed in European tissue banks (in all the countries involved in the project) was performed by means of a questionnaire. Another study was performed, also through a questionnaire, to diagnose the capability of tissue establishments to follow the European Directives on tissues and cells. As a result of the different studies performed and the compilation of results from the remaining working groups regarding the registry data and the training and audit models, the key quality and safety points for tissue banking activities were detected and, consequently, the Guide of Recommendations has been produced.

2. Objectives and results achievement.

The main tasks of WG1 have been the following:
1. Perform a comparative analysis of the different standards followed in the participating countries to detect the tissue banking quality and safety key points. Define the number of standards or guides followed and quantify the differences and similarities among them.
2. Study the rate of implementation of the European Directives on Tissues and Cells.

➢ **1ST WORKING PERIOD**

To analyse the different standards or guides followed in the different European tissue banks as a tissue bank quality and security system. The aim was to obtain information on which were the most commonly followed standards and detect any problems that could have arisen implementing those standards. Each bank established its protocols which defined their activities according to the different standards written by diverse scientific organisations. The analysis was focused on finding similarities and differences among the tissue banks protocols, and this study was used as the basis for detecting the quality and safety key points. A study of the rate of implementation of the standards followed by the different banks was performed using a comprehensive questionnaire with excellent response rate from the partners. The results of the analysis were reported in April 2005, and presented in the first interim report: WG1 presentation showed which were the most followed standards and the percentage of implementation of each partner country (EATB standards, AATB standards, etc.). In September 2006, the EC sent a letter asking for some lacking or unclear information, which was provided to the EC in a report on September 2006. It is important to mention in this section that, during the last working period, the EC sent a letter to the project promoter asking for the missing information on this study. A response was provided in September (please see the document sent on September 2006 for the complete comparative analysis of the results of this study).
To diagnose the capability of the participant tissue banks to accomplish the European Directive

During the second working period, from July 2005 to July 2006, another questionnaire was meant to be developed in order to study the capability of the participating tissue establishments to accomplish the European Directive on Tissues and Cells, studying as well each country’s regulations and everyday tissue banking practices. However, this was not accomplished during this working period. It was decided to leave this task for the last working period, from May 2006 to May 2007, since the EC communicated that it was preparing two technical annexes to the 2004/23/EC Directive of 2004. The EQSTB partners realised that it would be of much more interest to perform this study on the rate of implementation of EU Directive once all the annexes were out (2006/17/EC and 2006/86/EC). The results of this analysis is shown on the ‘3rd working period’ section.

To define the Quality and Safety Key Points

During the second working period most of the quality and safety key points for tissue banking activities were detected. The Quality and Safety Key points were one of the main topics of the second meeting held in Bologna to which all project partners attended.

The Key points groups were defined as follows:

1st Key point group: Donor
2nd Key point group: Tissues and Cells
3rd Key point group: Release and Allocation

In each key point group the most important specific key factors were selected and defined. To each specific keypoint a proposed action was described. Further it was decided which WG would be responsible for each key point, and justification was added; a plan was made to make each partner of the project responsible for a certain keypoint/task.
The following table was developed:

### WG I. Safety and Quality KEY POINTS

<table>
<thead>
<tr>
<th>KEY POINT</th>
<th>PROPOSED ACTION</th>
<th>RESPONSIBLE WORKING GROUP</th>
<th>JUSTIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor form</td>
<td>Should be harmonized, preferably a common donor form should be proposed and adopted</td>
<td>1</td>
<td>The donor form shall contain the basic data for safety and quality of the donor screening and evaluation.</td>
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<tr>
<td>Common definition of donors</td>
<td>To define: • Live donor • Cadaveric donor • Surgical residues donor</td>
<td>1</td>
<td>A uniform glossary is needed as all need to know exactly, what they are dealing with.</td>
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<tr>
<td>Donor evaluation</td>
<td>To set up a list of actions¹ included in the donor evaluation process and assign responsibilities for each step and for the final decision</td>
<td>1+ 4 3</td>
<td>The donor evaluation is the most important quality and safety key point in the donation process.</td>
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<tr>
<td>Donor testing</td>
<td>To set up a list of basic and additional donor testing methods</td>
<td>1</td>
<td>Testing is the second most important quality and safety key point in the donation process. Both donor evaluation and testing should be at the same level in all the establishments participating in the project.</td>
</tr>
<tr>
<td>Procurement</td>
<td>Depending on the procurement method, premises and personnel should be defined</td>
<td>1</td>
<td>Selection of appropriate procurement methods, description of facilities, and trained personnel are the most important quality and safety key points.</td>
</tr>
<tr>
<td>Records and registers</td>
<td>Basic forms and registers should be designed to assure full traceability of products</td>
<td>1 + 2</td>
<td>Defining and setting up basic data for full traceability shall be mandatory.</td>
</tr>
</tbody>
</table>

¹ Actions should include: review of the donor’s medical documentation, review of the donor’s history (personal, travel, social, behavioural etc), physical examination, blood samples collection, evaluation of the testing results, final decision-making about eligibility.

### TISSUES / CELLS

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<th>TISSUES / CELLS</th>
<th>PROPOSED ACTION</th>
<th>RESPONSIBLE WORKING GROUP</th>
<th>JUSTIFICATION</th>
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<tbody>
<tr>
<td>Transport of procured tissues and cells to TEs</td>
<td>Describe logistics and transport conditions. Validation of transport conditions.</td>
<td>1</td>
<td>Transport conditions can influence the safety and quality of the tissue and cells therefore they shall be clearly defined and validated.</td>
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<tr>
<td>Reception of tissues and cells to TEs</td>
<td>Setup a quality and safety checklist for reception</td>
<td>1</td>
<td>Tissues and cells received to TEs shall meet essential safety and quality criteria.</td>
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<tr>
<td>Coding</td>
<td>Prepare model catalogues of tissues/cells and products</td>
<td>2</td>
<td>For each donor, tissue/cell and tissue/cell product a unique identifier shall be assigned.</td>
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<td>Data protection</td>
<td>Define criteria how to assure that unauthorized persons will not have any access to the TEs data</td>
<td>2 + 4</td>
<td>Data on donors, tissue, distribution etc. shall be protected in order to prevent...</td>
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<tr>
<td><strong>Environmental conditions</strong></td>
<td>Define requirements for environmental conditions for particular tissues / cells and processing methods</td>
<td>1 + 4</td>
<td>Processing environment shall assure that the final product will meet the pre-defined quality and safety criteria</td>
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<td><strong>Processing, preservation, packing and storage of tissues and cells in TEs</strong></td>
<td>Common guidelines for elaboration of SOPs GTP manual for processes authorization</td>
<td>1 + 4</td>
<td>Although SOPs should be strictly individual for each TE depending on their premises and processing methods, the frame for the SOPs can be common.</td>
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<tr>
<td><strong>Good Tissue Practices</strong></td>
<td>GTP manual for processes authorization</td>
<td>1 + 4</td>
<td>GTP manual should be useful</td>
</tr>
</tbody>
</table>

| **Allocation** |
|-----------------|-------------------------------------------------|-------|--------------------------------------------------------------------------------------------------|
| **Waiting list** | Criteria for: *Emergency waiting list* *Waiting list* *Decision-making for allocation* | 4 | A uniform policy for establishment and management of waiting lists is desirable. Priorities shall be based on medical needs only |
| **Release procedures** | Decision-making, quality control of the final product, responsibilities, product validation at release | 1 + 4 | There shall be assurance that only safe and high quality products are released for use |
| **Register of recipients / recipient institutions** | Register setup, Which data shall be managed | 2 | Important key point for full traceability |
| **Export – import policies** | Export-import of tissues and products: *To – from EC countries* *To – from third countries* | 1 | Exports-imports of tissues/cells and products only from facilities with the same or higher level of safety and quality |
| **Serious adverse events / reactions reporting policy. Corrective actions** | *System, responsibilities and timing, for SAE and SAR reporting* *Reporting forms* *Information on corrective actions* | 4 | SAE and SAR shall be reported to competent authorities and all partners. A system of tissue/cell vigilance should be established |
| **Errors and accidents reporting policy. Corrective actions** | *System, responsibilities and timing, for errors and accidents reporting* *Reporting forms* *Corrective actions* | 4 | All non-conformities pertaining to processing/preservation shall be reported along with information on corrective actions |
| **Inspections** | Uniform guidance for TEs inspections and audits | 4 | Inspections and audits represent very important and integral quality issues |
| **Training of personnel organization** | Elaboration of teaching and training programs for TEs staff/personnel | 3 | Teaching and training of staff shall be harmonized |

This table was very helpful in guiding each working group to begin describing and explaining in detail the quality and safety key points that were assigned to them.
To prepare the outline and the first draft of the Guide of Recommendations (further as Guide).

Once the quality and safety key points were detected, each working group was made responsible for them. Each partner began to describe in detail the quality and safety key points that were assigned to them. A preliminary draft of the Guide was developed (which was presented in the second interim report). At this point, the Guide was made up of the quality and safety key points shown on the table above, as well as of a description of the results of the first questionnaire that was made in order to detect the standards followed, and thus, the key points.

➢ 3rd WORKING PERIOD:

To prepare, finalize and publish the final version of the Guide of Recommendations

At the beginning of the last working period, the draft Guide of Recommendations was a result of the following tasks that had been achieved:

a. Identification, recompilation and study of Standards, Guides and Code of practices followed in partner institutions.

b. Pointing out the differences and similarities among different European tissue banks in the application of the various standards analysed

c. Identification of the Implementation rate of the standards among the banks.

d. Analysing of key factors that may influence safety and quality on tissue transplantation.

e. Working out of the recommendations for tissue banking activities

During the period from August 2006 until March 2007, the Guide of Recommendations was greatly improved. It was decided that the Guide should not only contain the Quality and Safety key points, but also other practical information which would be very helpful of tissue banks (and also to help experts in tissue
banking that might want to create a tissue bank and do not know how to begin. Thus, the Guide was structured into 4 main sections:

1. **Quality System**: A description of the different quality systems which apply to tissue banking (ISO, GMP, GTP), and provision of the general quality system requirements.

2. **Legal and Regulatory Framework**: The legal and regulatory framework covering tissue banking activities in Europe, stating their requirements and deadlines (European Directives on Tissues and Cells).

3. **Standards**: A description of the different standards on tissue banking activities which are available in Europe (EATB standards, Council of Europe’s Guide to safety and quality assurance for organs, tissues and cells, and the World Health Organisation’s standards).

4. **Quality and Safety Key Points**: Recommended quality and safety key points in tissue banking that we as experts consider fundamental in order to work in such a way as to ensure the quality and safety of tissue grafts for transplant.

At this point, the EC already published all the technical annexes of the EU Directive from 2004. Hence, this Guide has taken much into account Directive 2004/23/EC and its technical annexes 2006/17/EC and finally 2006/86/EC. A deep analysis of these Directives was performed, which was very important to detect and describe all the quality and safety key points on tissue banking.

On September 2006, the EC sent a letter to the project promoter asking for some further information from all the WGs which was lacking in the second interim report. A reply was sent on September 2006. The next month, a 2nd letter was received by the project promoter, in which the EC provided very helpful suggestions for the Guide of Recommendations. These suggestions, which were followed and included in the Guide, are shown below:
1. **The Guide must be more user-friendly:** it should be a well-structured and integrated text so that tissue banks can easily consult the quality and safety key points. Include flow charts which visualize the Q&SKP. Per issue discussed, information should be given on what is understood by the keypoint (for example, if the Directive requires SOPs, explanation should be given on what are SOPs and also on how to develop them).

2. Reference should be given to where additional information on the issue can be found (including links to relevant websites).

3. The definitions used in the Guide of Recommendations must be in line with the EU Directives on Tissues and Cells.

4. The English language of the Guide needs to be checked by a native speaker.

At the beginning of the year 2007, it was decided to create more key points and also to create another main group of key points, the ‘General Concepts’, since it was detected that there were a few main aspects/topics that affected all (or most of) the process of tissue banking, which were not specific of each process (it was not necessary to describe them in detail in the other keypoint groups). In April and May of 2007, the external auditors that performed the final technical audit of the project also provided some useful comments and suggestions on certain key points and on the draft Guide of Recommendations. As a result, the final list of key points was obtained, which is the following:

**Key Point Group 1: General Concepts**
- Standard Operating Procedures (SOPs)
- Good Tissue Practices (GTPs)
- Data protection
- Coding
- Environmental Conditions
- Validation of processes
- Organisation of Personnel Training
- Audits and Inspections
- Third Party Agreements

**Key Point Group 2: Donation and Procurement**
- Common definitions of donors
- Donor Selection and Evaluation
- Donor Testing
Key Point Group 3: Tissues and Cells
- Transport of procured tissue to TE
- Reception of tissues at TE
- Processing, preservation, packaging and storage in TEs

Key Point Group 4: Release and Allocation
- Release procedures
- Waiting list
- Register of recipients / end user institutions
- Export / Import policies
- Serious Adverse Events / Reactions reporting policy and Corrective Actions

As can be observed above, the title of the second group of key points was changed for a better understanding of the scope of that group: it was modified from ‘Donor’ as it was in the first draft of the Guide, to ‘Donation and Procurement’ in the final Guide.

All the key points shown above were much more detailed as compared to the initial draft presented in the second interim report; the final Guide is also more user-friendly than the initial one, as it is structured in a very coherent way and it is much more detailed and complete.

Likewise, in February 2007, electronic correspondence was kept with the EC, and more excellent suggestions on the 4 sections of the Guide (Quality System, Standards, Regulatory Framework and Q&SKP) were provided by them.

On May 2007, the final Guide of Recommendations was obtained (please see the following document: Guide of Recommendations for Tissue Banking). The Dissemination section of the promoter part of this final report explains in detail the process of design and editing of the Guide.

Study of EU Directives rate of implementation
During the last working period, WG1 prepared a questionnaire which was sent to all project partners in order to study the implementation of the EU Directives in the participating countries. This questionnaire was passed, not only to project partners,
but to other experts as well: those partners who are national authorities asked external tissue banks in their country to fill in the questionnaire so that the project results could expose more broadly the situation in all the participating countries. During the final meeting which was held in Barcelona between the 15th and 17th of February, WG1 presented the results from the study of the rate of implementation of the EU Directives in the participating countries (please see Annex D3 for WG1’s presentation). The results of the study show that most partners had more or less already adopted the EU Directives, or were in the process of adopting them. For a complete analysis of the results of this study, please see Annex O1.

» Transferability of WG1 results

Guide of Recommendations
All the project partners recommend that the Guide of Recommendations is updated from now on, as further knowledge and new Directives on tissue banking appear. It would be interesting that there is a body, or perhaps an organisation, that takes on this task.

Directive implementation rate
We believe that it would also be interesting for the European Commission to have continuous knowledge of the rate of implementation of the Directives in the Member States. For this purpose, perhaps it would be interesting to have an organisation perform these studies every ‘x’ months, and provide the Commission with the results.

» Incidences and deviations regarding the achievement of the objectives:

1. Semantics misunderstanding nº1: Standards vs. Directives
   On page 27 of the project proposal, under the description of tasks (1c) it said: “implementation rate of the standards among four banks”. Here there was a semantics misunderstanding, since we meant Directive instead of standards.
This issue was cleared up to the Commission on September 2006, when a letter was sent to it responding to their different questions.

It is important to mention that two different studies were performed by WG1. One was the study of the comparative analysis of the different standards that are available among the participating partners (EATB, BATB, AATB, etc.). This study and its results were presented in the first interim report, and complemented in the document sent to the EC on September 2006. The second study that was carried out was the study of the rate of implementation of the EU Directive among the partners. This study was performed later on and it was presented to the partners in the final meeting in Barcelona.


We did not aim to elaborate Standard Operating Procedures for all banking processes, because we understand that the existing ones are covering the area of tissue banking scientific criteria. All the project partners made a consensus during the project development that we would aim to provide the set of quality and safety key points that we, as tissue bank experts that created the consortium, consider to be indispensable in a tissue bank regular basis, establishing the “key points” on quality and safety that a tissue banker has to keep in mind. In order to develop this quality and safety keypoints, WG1 deeply analysed the current situation of the existing standards on tissue banking.

This issue was cleared up to the Commission on September 2006, when a letter was sent to it responding to their different questions.

3. Rate of Implementation of EU Directives: A questionnaire was prepared by WG1 to study the rate of implementation of the European Directives, which was given to WG4 (in charge of sending and compiling the questionnaire). The questionnaire was sent and filled in by all partners (those that are national authorities passed on the questionnaire to external tissue establishments so that a more broad idea of the implementation rate in the countries was obtained). The results were compiled and sent back to WG1 for
further analysis. The analysis was presented by WG1 during the final meeting in Barcelona in February 2007. This task was meant to be achieved during the 2nd working period, however, it was decided to wait until the next period because the EU was going to publish in November 2006 the two technical annexes to the Directive 2004/23/EC - 2006/17/EC and 2006/86/EC); it did not make sense to perform the study of the implementation rate of the Directives if all the Directives on tissues and cells were not yet published. (Please see Annex D3 for the presentation of WG1 showing the results of the rate of implementation of EU Directives, and Annex O1 for the thorough analysis of the results from this study).

3. Execution of other activities.

2. Answer all the requirements from the EC and sent them to the leader of the project, which was then sent to the EC (in September 2006).
3. Attendance to the final meeting held in Barcelona on February 2007. (Please see WG1 Presentations: Annex D3 and D7)
   - Jan Koller: Ruzinov General Hospital Bratislava, Slovakia
   - Olivier Cornu: Belgian University Tissue Bank, Belgium
   - Bernard Loty: Agence de la Biomèdecine, France
   - Arnaud de Guerra: Agence de la Biomèdecine, France

4. Future Activities

a) Dissemination of the Sanco-EQSTB Project, the Guide of Recommendations and the Guide for Auditing Tissue Establishments in diverse local, national and international meetings.
During the last part of this working period, the *Guide of Recommendations* has been published. 2000 copies have been printed. Some of these have been distributed to all project partners; the rest will be presented and provided to professionals at various international, national and local meetings until the end of the year. The idea is to continue disseminating the Guide until all the copies are distributed. Please see the Project Promoter section of this final report (page 19) for more information on the dissemination of the *Guide for Auditing TE*. 
WORKING GROUP 2 ACTIVITIES EXECUTION – REGISTRY

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   - Tasks
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     - 2
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   - Final Results and Conclusions from all objectives
   - Transferability of WG2 results
   - Incidences and Deviations
3. Execution of other activities
4. Future Activities
1. Introduction to WG2

Group members:

Coordinator: Pier Maria Fornasari, Istituto Ortopedici Rizzoli, Italy.
Co-coordinator: Alessandro Nanni Costa, Centro Nazionale Trapianti, Italy.

Participants:
- Virgil Paunescu, Medecine University Victor Babes, Romania.
- Ioana Siska, Medecine University Victor Babes, Romania.
- Martii Hirn, Tampere University Tissue Bank, Finland.
- Norbert Franz, Deutsches Herzzentrum Berlin, Germany.

People involved in the analysis and software development (CNT):
- Eliana Porta, as tissue expert
- Francesca Vespasiano, as IT expert that has set up the prototype
- Claudia Ferraro, as administrative manager

IT Technicians from Hospital Clinic of Barcelona:
- Raimundo Lozano
- Felipe Geva
- Sandra Vidal

Tasks:
The main objective of this working group was to define a prototype of a Registry Network Database (and make it available on the Internet) which comprises the entire tissue banking process, as well as the common nomenclature needed to create it and observe whether it would be possible to exchange tissues between European tissue establishments with such a registry. For this matter, different data sheets were developed (donor, tissue, allocation and transplantation data sheets), all the variables were detected and defined, and the product list for the chosen tissue was harmonised. One type of product was chosen to develop the Registry prototype, which was frozen musculoskeletal tissue.
2. Objectives and results achievement.

The three specific objectives of this working group are the following:

1. Define the common terminology and variables of tissue banking in order to create the common Registry to observe the possibility of exchanging tissues between tissue establishments throughout different European countries.

2. Define a prototype of a Registry Network Database for the entire tissue banking process: donation, processing, preservation, traceability, clinical application and adverse reactions after transplantation.

3. Make available the database on the Internet with a Search Function and validate the Registry prototype through a pilot data charge.

Next is an image which comprises the timeline of the objectives’ achievement.

Image 1: Work Flow
1. Define the common nomenclature for the Registry database

**First Working Period**

During the first working period, the preliminary tissue terminology and variables to be used in the prototype registry were agreed. During the first meeting, which was held in Barcelona on December 2004, it was decided that only one tissue would be chosen in order to develop the prototype of the Registry: frozen musculoskeletal tissue (MST). The reason for choosing this tissue is that it is the most common tissue among all project partners. Also because the objective of the registry is to validate the variables needed for international exchange of tissues and, for this matter, it is not necessary to perform this task with all kinds of tissues. Moreover, it was seen that during the life of the project, it would not be possible to do such a thing.

To achieve the objectives set, WG2 based its tasks on the quality and safety key points that were detected by WG1 regarding a registry for tissues. These key points were the following:

<table>
<thead>
<tr>
<th>DONOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records and registers</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TISSUES / CELLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coding</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

| Data protection | Define criteria how to assure that unauthorized persons will not have any access to the TEs data |
| Data protection | Data on donors, tissue, distribution etc. shall be protected in order to prevent unauthorized disclosure, deletion or modification |
|       | II + IV |

<table>
<thead>
<tr>
<th>ALLOCATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Register of recipients / recipient institutions</td>
</tr>
</tbody>
</table>
The registry network database was also defined by means of analysing all the internal processes that are carried out in TEs, analysis and development of a logical and physical schema of the database, and an analysis of the functional needs in order to set out the prototype on the Internet. The image below shows the design of the Registry prototype for musculoskeletal tissue banks.

Consequently, an important group of variables that comprises all tissue banking processes was obtained, which is the following:

- donor
- donations
- tissues
- traceability
- allocations
- transplant
- adverse reactions after transplantation
Second Working Period

As a result of the group of variables obtained, the data set was defined during the second working period (January 2006). 4 data sets/sheets were defined:

1. Donor data
2. Tissue data
3. Allocation data
4. Transplant data

<table>
<thead>
<tr>
<th>DONOR variables</th>
<th>Country</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDENTIFICATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bank</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td></td>
<td>Running n. by the bank/year</td>
</tr>
<tr>
<td>DATE OF BIRTH</td>
<td>dd/mm/yyyy</td>
<td></td>
</tr>
<tr>
<td>AGE</td>
<td>numeric</td>
<td></td>
</tr>
<tr>
<td>GENDER</td>
<td>M/F/u.k.</td>
<td></td>
</tr>
<tr>
<td>BLOOD GROUP</td>
<td>A/B/0/AB</td>
<td></td>
</tr>
<tr>
<td>WEIGHT</td>
<td>numeric</td>
<td></td>
</tr>
<tr>
<td>HEIGHT</td>
<td>numeric</td>
<td></td>
</tr>
<tr>
<td>TYPE OF DONOR</td>
<td>Living/h.b./non h.b.</td>
<td></td>
</tr>
<tr>
<td>HISTORY EVALUATION</td>
<td>Free text</td>
<td></td>
</tr>
<tr>
<td>DONATION DATE</td>
<td>dd/mm/yy</td>
<td></td>
</tr>
<tr>
<td>SEROLOGIES</td>
<td>VIROLOGIES</td>
<td>MICROBIOLOGIES</td>
</tr>
<tr>
<td>NEG</td>
<td>NEG</td>
<td>NEG/NEG after irradiation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TISSUE variables</th>
<th>Country</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDENTIFICATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bank</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donor code</td>
<td></td>
<td>Running n. by the bank/year</td>
</tr>
<tr>
<td>INTERNAL TISSUE CODE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TYPE OF TISSUE</td>
<td>Agreed List of tissue</td>
<td></td>
</tr>
<tr>
<td>EXPIRATION DATE</td>
<td>dd/mm/yyyy</td>
<td></td>
</tr>
<tr>
<td>NOTE ON RETRIEVAL</td>
<td>Free text</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ALLOCATION variables</th>
<th>Country</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDENTIFICATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bank</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DATE OF ALLOCATION</td>
<td>dd/mm/yyyy</td>
<td></td>
</tr>
<tr>
<td>DESTINATION</td>
<td>Hospital/bank</td>
<td></td>
</tr>
<tr>
<td>TISSUE DELIVERED</td>
<td>Selection from the available tissues inserted</td>
<td></td>
</tr>
</tbody>
</table>
During the second meeting held in Bologna on November 2005, all project partners agreed on the consensus of the common nomenclature:

1. variables
2. data sets
3. list of tissues

Last Working Period

During the final working period, some modifications were done to the 4 data sets that had been produced. The final 4 data sets are shown below:

Donor Data Form:
Tissue Data Form:

![Tissue Data Form](image)

Allocation Data Form – General data:

![Allocation Data Form - General data](image)

Allocation Data Form – Data of tissues:

![Allocation Data Form - Data of Tissues](image)
During the last working period, from May 2006 to May 2007, different suggestions were provided by the partners that performed the pilot data charge regarding the musculoskeletal product list. As a result of these suggestions and discussions among the partners, the final product list was obtained, which is as follows:

- Acetabulum
- Iliac Crest Wedge
- Proximal Femur
- Distal Femur
- Femoral condyle
- Proximal Humerus
- Proximal Tibia
- Tibia condyle
- Diaphysis femoral/humeral/tibial < 15cm
- Diaphysis femoral/humeral/tibial > 15cm
- Femoral head < 100gr.
- Femoral head > 100gr.
- Fibula shaft
- Cancellous chips
- Wedge
- Other bone (specify)
- Achilles tendon
- Gracilis tendon
- Tibia tendon
- Semitendinosus tendon
- Patellar Tendon
- Other ligament / tendon
- Meniscus
- Fascia lata
Other modifications that were made to improve the product list are the following:
- A box for comments was added on the tissue data set: ‘notes on retrieval’
- The possibility to chose between ‘left’ and ‘right’ bone was added (drop down list)

**Product List Definitions**

The EC requested that we provide a set of definitions of the musculoskeletal products which appear in the list. Annex P1 shows the tissue bank definitions of the product list detailed above, including anatomical definitions of these products, which have been obtained from the Medline Plus Encyclopaedia online. The images have been obtained from the Transplant Services Foundation (TSF) and Lifenet websites, and the Biomet online catalog.

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**2. Define the prototype of a Registry Network Database**

**Second Working Period**

During the end of the second working period, the database and the web application were developed. A search engine function was created and made available for all the participating tissue establishments; this system was very helpful for the different banks to simulate an exchange of tissues among them (different members of the European Union).
The database and the web applications were put on-line for the first test on June 2006. Please see Annex P2 for the description of how to use the Registry database.
During the last working period, the general indication for the development and management of a computerised registry for tissue establishments was defined. It is as follows:

*General indication for the development and the management of a computerised registry for tissue banks:*

The development of an application which allows the registration of a tissue bank's internal processes, taking into account the different phases (donation, allocation and transplant of tissues – known as “Registry”), requires different steps before and after the setting up (in the long term) for the maintenance, and above all for the protection and safety/security of the data, in case of possible losses.

- The preventive phase is extremely important. This means the analysis of the different aspects involved in the choice of which data system platform to use (economic resources, distribution of the tissue bank personnel, availability of IT personnel in the bank - system analysts and programmers - and whether or not servers are owned by the bank or subcontracted to third parties outsourcing these services.) Once this choice is made, the deployment phase can start.

- In the deployment phase, certain technical requirements should be taken into account in order to set up a system for data input. These requirements should take into account EU directives and in particular the 2006/86/EC (annex 1, sect. E):

  - **Data Traceability**
    The code for the retrieved tissue should be linked to the related donor (traceability is ensured by the matching of donor code - tissue code and vice versa). In addition to this match in the system, a univocal identification code (donor- tissue) can be
inserted. This code is registered in the record of the next step in the allocation process for that tissue.

The allocation also has a univocal code. Furthermore from the allocation identification code it is possible to trace back to the donor (allocation - tissue - donor and vice versa). If the allocation is being made to a recipient for transplant purposes and not to another bank, through the allocation code we can trace back to the donor again (recipient allocation tissue donor and vice versa).

**Data traceability is ensured:**

- **Quality of the Data:**
  Creation of a guide which will guide the user by inserting the data (e.g. with pre-loaded data in list-boxes if the data are already pre-coded, as with the list of tissues) or through the alerts. Some automatic controls are extremely important when the data on the single form are sent, in order to reduce the risk of error in data input.

- **Integrity Of The Data:**
  “Temporarily” guided input: e.g. in order to ensure data integrity and traceability of the process, you would only be able to insert data relating to a retrieved and stored tissue if you had already inserted the information on the tissue donor and linked it (the tissue) to him/her (the donor).
- **History of Modification:**
  Each piece of data inserted should be “marked”: when the data is sent, the system automatically registers the user who has carried out the operation and the date/time. This takes place each time a modification is made. Thereby it should also be possible to trace back the “history” of the data (2006/86/EC annex 1 sect. E point 4).

- **Safety and Security in Data Access:**
  The system should be accessible ONLY to authorised users. (2004/23/EC and subsequent 2006/86/EC Annex I sect. E point 8). Authorised users are only those already registered in the system in an ad hoc table who have received a user id and a password. It is important that the user be able to autonomously modify his/her password. For additional safety and security, it is also advisable to build in periodic expiry of the password in order to compel the user to change his/her password periodically (another element of the system should be deactivation of the user if he/she does not enter into the system within a predefined period). Also taking into account the European Directive, there should be different degrees of access within the registry (profiles), meaning that people with different roles and functions in the tissue bank have different levels of access to the system functions: some users would only be able to visualize the data, whereas others would have access to input/modify; or some users would only be able to visualize certain data (based on privacy policies, if not necessary, some users may be excluded from visualizing sensitive donor data) whereas other users may have full access to all data. The ideal solution would be to provide each authorised user with a smart card. Each smart card would be linked to a digital certification issued by a legally recognized Certification Authority which associates the person’s identity with an “electronic key” in his/her own personal smart card. The
application manages and allows access only to those certified (already recorded in the database). Once the system has been deployed, the safety and security issue should be taken into account, especially the protection and physical preservation of the data. Some measures to ensure these aspects should be put into practice:

a) The computer in which the Database is installed (data server) should have all the security features against external access and viruses (firewall and antivirus) set up by technicians responsible for maintenance and periodically checked and updated by them.

b) Only authorised personnel should have entry to the rooms housing the server and these areas should be locked and put under 24-hour surveillance.

c) In the event of adverse events causing damage to the Database, data should be restored as soon as possible in order to ensure the integrity of the information (see 2006/86/EC annex 1 sect. 3 point 3). This means planning for what is technically called “disaster recovery procedure”. This entails building in a procedure for daily back up of the Database, possibly on electronic storage medium (e.g. DVD or magnetic tape), to be stored in an area apart from where the central server is located, in purpose-built fireproof rooms which are also only for authorised personnel.

3. Validation of Registry database through a pilot data charge

**Last Working Period**

During this last working period, the Registry has been validated through a pilot data charge performed by 4 participating tissue establishments. These banks were the following:
1. BIS Foundation, Netherlands; Responsible: Theo de By
2. TSF, Spain; Responsible: Aurora Navarro and Esteve Trias
3. TUTB, Finland; Responsible: Martii Hirn
4. BTM-IOR, Italy; Responsible: Pier Maria Fornasari

The validation test was concluded with a positive feedback provided by all the partners involved in the data charge. Very useful suggestions and observations were received from Martti Hirn (TUTB), Clara Fernandez (TSF) and Arlinke Bokhorst (BIS).

The participating partners introduced approximately 350 musculoskeletal tissue grafts each into the database. The pilot data charge finalised in March 2007. As mentioned in the previous section, after this task had finalised, some modifications were made to the product list, improving it in order to make a data charge more efficient and easygoing.

The results and conclusions of the data charge were presented at the final meeting in Barcelona in February 2007 (see Annex D4 for WG2’s presentation). 358 donors have been inserted (23 non heart beating, 334 heart beating and 1 living) to test the registry. Likewise, 1169 tissue grafts have been inserted (90 already delivered and 1079 ready for distribution). An exchange of information and suggestions from all partners was obtained during the final meeting of the project.

**Final Results and Conclusions from all objectives:**

1. **Building a tissue registry through the multinational European network database**
   - Standardised data were agreed to receive the same information from different tissue banks with regard to donor selection, tissue retrieval, processing and transplantation.
• A list of products for one type of tissue (frozen musculoskeletal) was defined. During the pilot data charge, some problems arose, which meant that suggestions from the different partners were given to WG2 to make the corresponding changes in order to improve the registry variables and ease and facilitate the exchange of tissues among different countries.

• A way to attribute a code number was decided for ‘donation’ (see the section “Incidents and deviations”).

2. Building a database to obtain a prototype of a registry for frozen MST tissue and the sharing of information between tissue banks.

• The registry was put online
• A search engine was created to allow sharing of information
• The testing performed by four tissue banks proved that it could be easily used
• The database was compliant with the requirements for data safety and protection:
  − The data server is in a network DMZ where the connections to this server occur through a Firewall (of Hospital Clinic de Barcelona), therefore the server is only accessible to authorised personnel.
  − Only authorised personnel could enter the rooms where the server was placed, and those rooms were locked and put under surveillance 24 hours.
  − There is a procedure of daily back up of the Database on an electronic storage medium, stored in different rooms from where the central server is located, in ad hoc fireproof rooms which are also accessible to authorised personnel only.

**Transferability of WG2 results**

The objective of WG2, which has been to develop a prototype of a frozen musculoskeletal tissue registry, has been achieved. During the project, it has been detected that what has made this task most difficult is the harmonisation of the
nomenclature of the tissues. There are many tissue establishments in Europe in which each one uses a different system of defining their products; to obtain a common nomenclature of tissues has been quite a challenge. For this reason, we believe that it would be very interesting to have a common codification system of tissue products in Europe. This fact would much facilitate to have a European registry in order to be able to exchange tissues among different member states.

**Incidences and deviations regarding the achievement of the objectives:**

1. On September 2006, the European Commission sent the project promoter a letter regarding some issues that were still pending from the previous interim report that the EC wanted to clarify. Regarding WG2, there was an observation which had to be clarified (the *common coding system* issue:

   - How to attribute a code number was decided for the ‘donation’. It does not seem useful to have code numbers for each product: it would not guarantee a higher level of traceability, (which has to be assured by each Bank (MS)). A common terminology was agreed; however, a wide consensus would be necessary to create common code numbers, and this would require too much time which, during the life cycle of the project, would not be possible. Taking into account the complexity of a coding system, a specific project would be necessary to elaborate a common coding system for all tissues in all tissue establishments.

   As far as this project is concerned, and in order to achieve the objective of seeing whether it would be possible to exchange information between tissue establishments, the aim was to arrive at a consensus on the minimum data sets to define.

2. Another incidence, which has been mentioned earlier, is that the EC recently asked to provide not only the product list, but also definitions of these products. In this report we provide these definitions (Annex P1).
3. Execution of other activities.

- Contribution in the *Guide of Recommendations* for the part related to its tasks, which are the following keypoints:
  a) Records and Registers
  b) Coding
  c) Data Protection
  d) Register of recipients / recipient institutions

These tasks include the definition of the data that should be collected in a tissue registry, the coding necessary to ensure data traceability, the data safety and security measures, definition of how a tissue bank registry must be kept, which data must be put in to guarantee full traceability and compliance with the ED, and finally a description of how forms should be in order to collect information on donor/donation/tissues and cells/ transplantation.

- Answer all the requirements from the EC and sent them to the leader of the project, which was then sent to the EC (in September 2006).

- Contribution to the *Guide for Auditing Tissue Establishments*.

- Attendance to the final meeting held in Barcelona on February 2007. (Please see WG2 Presentation: Annex D4)
  a) Claudia Ferraro: CNT, Italy
  b) Francesca Vespasiano: CNT, Italy
  c) Eliana Porta: CNT, Italy
  d) Martii Hirn: Tampere University Tissue Bank, Finland.

- Participation in dissemination activities of the *Guide of Recommendations* and the *Guide for Auditing Tissue Establishments* in different national and international meetings.

4. Future Activities

a) Dissemination of the Sanco-EQSTB Project, the Guide of Recommendations and the *Guide for Auditing Tissue Establishments* in diverse local, national and international meetings.
WORKING GROUP 3 ACTIVITIES EXECUTION – TRAINING

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1. Introduction
   - Group members
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   - Measurement of the knowledge of attendants
   - Validation of the training model through a pilot experience
     - Training model
     - 2\textsuperscript{nd} evaluation of participants’ knowledge
     - Final adaptations done in training model
     - Evaluation of the course
   - Final Conclusions for the training course
   - Transferability of WG3 results
   - Incidences and Deviations
3. Execution of other activities
4. Future Activities
1. Introduction

Group members:
Blanca Miranda, Organización Nacional de Trasplantes, Madrid, Spain.
Artur Kaminski, National Center of Tissue and Cell Banking, Warsaw, Poland.
Izabela Uhrynowska-Tyszkiewicz, National Center of Tissue and Cell Banking, Warsaw, Poland.
Jeroen Van Baare, Netherlands Bone Bank Foundation, Holland.

Tasks:
The main goal of Working Group 3 was to design and validate a specialised training model among tissue bank personnel that could afterwards become the approved education model recommended for the European Union members. This model is based on the banking personnel’s profile and the knowledge and training needs detected. To reach the objective, a training program was designed and exposed to the other partners in Bologna during the meeting held from November 2nd to 4th, 2005. It was decided that the training program should have an online course and a face-to-face course; these courses should complement each other and the latter should include the practical aspects that the online could not:

- The on-line course is the so-called “International on-line Tissue Banking Course”, an adaptation of the course that the Virtual University of Barcelona developed with high success some years ago.

- The face-to-face course, to be held in the city of La Coruña (Spain) for two days, in the premises of one of the best Spanish laboratories, is optimal to carry out the practice and necessary part of this training. 28 participants from the different partners’ organizations would attend the course, 14 medical doctors and 14 technicians, apart from teachers and tutors. A preliminary Agenda was presented during the Bologna Meeting.

- These two Courses should be complementary so it would be compulsory to do both of them to get the knowledge and expertise that European Quality System for Tissue Banking Project wants to offer to tissue banking professionals with its training.
2. Objectives and results achievement

The objectives of this working group have been achieved through the following methodology:

1. Defining professional profiles and job descriptions
2. Detecting training needs
3. Creating the model of training
4. Measuring the knowledge of attendants
5. Validating the training program

1. Defining professional profiles and job descriptions

In order to elaborate a training model for tissue banking professionals, it was necessary to define professional profiles and job description cards of the main personnel in a tissue establishment. For this matter, WG3 developed a questionnaire which was passed to all project partners for completion. The questionnaire was analysed and it was seen that scientists and medical doctors were found to be in the majority of the staff involved in tissue establishments. Technical workers as well as nurses were also found in the group directly involved in tissue banking activities (fig.1).

Fig. 1. Professionals involved in tissue banking activities.
As a result of the analysis of the questionnaire, four main positions were detected and job description cards for those positions were developed. These are the following:

- medical director
- quality assurance manager
- procurement technician
- processing technician

2. Detection of training needs

The questionnaire that was distributed to all project partners for completion also included questions to detect the current knowledge of the tissue bank’s personnel and their training needs, since this information would be necessary to develop the training model. After analysing the questionnaire, these training needs were identified. The majority of tissue bank professionals pointed out the need of upgrading their knowledge in quality assurance, legal aspects and tissue processing and procurement procedures. Other aspects like microbiology, anatomy, IT systems and sterilisation procedures were less commonly requested (fig. 2).

Fig. 2. Educational needs of tissue bank personnel.
3. Creation of the Model of Training

As a result of the above evaluated indicators and analyses performed through the questionnaire, the training model was developed. This specialised European training model is addressed to tissue establishment workers and it is based on the tissue bank personnel’s profile and the detected training needs.

During the midterm meeting held in Bologna, it was decided and agreed among all project partners that the training model should be structured in two courses: one on-line course to last approximately 2 months, and one face-to-face course lasting 2 days. The combination of these two courses seemed to be an adequate methodology of training professionals in the tissue banking field. It was decided that a pilot training would be performed in order to validate the training program developed.

In order to develop this training model, a review of the existing tissue banking training courses was made. The IAEA developed a program named “Online Tissue Bank Program”, related to specific countries and focused to train people involved in IAEA activities (such as ionising radiation). This association also developed a course named “Training for Technologies in Tissue Banking” in a regional training centre in Singapore. The EATB has promoted educational courses through newsletters, meetings, and workshops that have taken place during these meetings. The Cardiology Centre Monzino (Italy), made a “Specialisation Course in Cardiovascular Tissue Banking”.

As mentioned above, the existing courses were detected and analysed; these were mainly regional and very specific ones. However, a general tissue banking training course did not exist, except for the “International On-line Tissue Banking Course” from the University of Barcelona, in Spain. Working Group 3 analysed this international course and agreed that it should be used as a basis for the training model, in order to give a general training on tissue banking that would cover all the different aspects, from general concepts to specific ones, on each tissue bank activity. The International On-line Tissue Banking course was not only designed to respond to a growing demand of health professionals of
Continuing Education related to the generation of tissues and cells for transplant, but also to help developing a global dynamic tissue banking organisation adapted to the up-to-date needs of society. Hence, this course seemed to fit extremely well with the aims of the project.

Therefore, the training model has been elaborated, firstly, by adapting this virtual course to the profiles and the training needs of the attendants involved. This was not a complicated task to do, since the contents of the virtual course adjusted rather well to the profiles and needs of the personnel. The contents of the course were adapted to the project’s necessities by asking all authors of the course to update the contents, based on the duties/functions and needs of the participants. Given that there were not any important differences among all the participants’ requisites, each main topic lasted approximately one week, except for the musculoskeletal and donor seminars, which lasted approximately two weeks (because of the requirements of the participants). (Please see section 5 for the entire course programme). The on-line course activities were specifically created for the new edition of the international online course; these activities were built in such a way that attendants would have to dedicate to it 1 hour a day during the 2 months in order to obtain proper certification.

After adapting the on-line course for this training model, WG3 developed the face-to-face course in order to complement it. The addition of this in-person course into the training model did not only cover the need for a practical course on procurement and processing procedures, but also to clarify some theoretical aspects as well as to create some practical simulation exercises to verify the knowledge gained by participants. Hence, the face-to-face course contains practical aspects on the donor selection, procurement and processing, interactive management skills, quality control training, as well as clinical and tissue bank cases to solve (please see section 5 for the detailed contents of the course).

The advantages of developing such a model of training are that all the aspects of tissue banking, both theoretical and practical, can be dealt appropriately. These benefits include the self-learning process with guidelines and tutors’ help, e-
learning contents procured by international experts and tutors trained to manage groups in the virtual campus, the reduction of geographical and time barriers, and the possibility to acquire expertise in practical terms. It is important to mention that the training should be carried out by qualified professionals in the tissue banking field who play a role as teachers and as tutors of the two courses. The tutors' role in the teaching methodology is to facilitate the learning process, to act as a guide in the learning process, to support the attendants and to answer their questions and doubts in real time.

4. Measurement of the knowledge of attendants
In order to evaluate the effectiveness of the training course, it was decided to perform two evaluations of the participants' knowledge and expertise in tissue banking, one before and another after the training courses were held. For this matter, a pre-evaluation questionnaire was developed which was completed by all the attendants before the training courses began. 25 surveys were received; the average score was 7.82 out of 10, with the highest grade being 9.68 and the lowest grade 5.81.

Likewise, after the training courses took place, the attendants were asked to complete a post-evaluation questionnaire (see next section).

5. Validation of the training model through a pilot experience

a) Training Model:
In order to validate the training model, a pilot training was performed. Both the on-line and the face-to-face courses took place during the second working period of the project. Tissue establishment workers of all the countries involved in the project have validated the training model through this pilot experience, by attending to both courses. There were 28 participants recruited on a voluntary basis, including tissue bank managing and technical personnel representatives from Belgium, Finland, France,
Germany, Italy, Latvia, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, The Netherlands and United Kingdom.

The contents of the entire training program are shown below:

- Tissue donor detection & selection criteria
- Quality assurance and control
- Tissue banking organisation
- Sterilisation of tissue grafts
- Eye banking
- Human amnion banking
- Cardiovascular banking
- Musculoskeletal banking
- Skin banking
- Stem cell and cord blood banking
- Gamete banking
- Pancreatic islets
- Ethical issues
- Regulatory issues
- Risk assessment & management
- Process validation
- GMP standards
- Health and safety in tissue banks

Some of these topics were only present in the online course, as some of them were only present in the face-to-face course, since it made sense that these topics should be distributed so. Most of them, nevertheless, were present in both courses.

The practical aspects that the on-line course lacked were covered and complemented by the face-to-face course, and vice versa.
On-line Training Course

The International On-line Tissue Banking course is a 40 academic hours training course (8 weeks) made up of different on-line tools designed to train tissue banking professionals during the development of the EQSTB Project. This course began on the 20th of March and it finished on the 28th of May, 2006.

The current on-line training course provides participants with up-dated, relevant and practical information on any aspects of special interest in tissue banking procedures from tissue donor detection and selection to tissue processing and distribution. The presence of International tissue bank specialists as authors and also lecturers guarantees a high level training experience.

The course develops a core structure with factual information based on written materials and audio-visual images, related with quiz evaluations and individual and group activities that promote learning. Communicating tools such as chats, forums and mails allowed participants, tutors and authors to interact, which permitted to clarify aspects of course development and to discuss the course contents.

Qualified professionals (52 authors and consultants) accurately prepared educational materials. Three trained tutors were specially prepared to attend in a personalized way accompanying students throughout the learning process. In E-learning modality, the tutors play a fundamental role because they follow participant’s evolution and guide them so that they can finish the course successfully. A close collaboration between faculty members, contents' authors and educational coordinators is established making easier the course’s dynamism. In order to achieve this aim, the tutors have to take a specialized course regarding this matter.

Below is an image of the virtual platform of the online course:
The virtual training material is structured in 10 modules for a better association and assimilation of concepts and explanations. Each module is focused on a relevant tissue banking aspect and contains visual and/or audio-visual resources in order to illustrate the explanation and make it clearer. These modules are the following:

**M1. Tissue Donation**
1.1 Tissue Donor detection and selection criteria.

**M2. Ethical Issue**
2.1 Ethical issue.

**M3. Regulatory issues**
3.1 Regulatory issues.

**M4. Quality Assurance**
4.1 Quality Assurance/Quality Control.

**M5. Tissue Banking**
5.1 Tissue banking general organization.
5.2 Sterilization of tissue grafts.

**M6. Cornea Banking**
6.1 Eye banking. Procurement, processing, storage.
6.2 Cornea banking. Clinical application.
6.3 Human amnion banking. Procurement, processing, storage and clinical application.
M7 Cardiovascular banking
7.1 Heart valve banking. Procurement, processing, storage and clinical application.
7.2 Vascular banking. Procurement, processing, storage and clinical application.

M8 Musculoskeletal banking
8.1 Cadaveric procurement.
8.2 Musculoskeletal banking. Living donation.
8.3 Processing, storage and distribution of lyophilised tissue.
8.4 Processing, storage and distribution of frozen musculoskeletal tissue.
8.5 Clinical application of musculoskeletal tissue.
8.6 Radiation sterilisation induced paramagnetic. Entities as a new marker of bone grafts.
8.7 Effectiveness of radiation – sterilized bone allograft in orthopaedic reconstructions.

M9 Skin banking
9.1 Skin banking. Procurement, processing, storage and clinical application.
9.2 Reconstruction of human skin on xenogenic collagen material.

M10 Miscellaneous
10.1 Stem cell and cord blood banking. Clinical application.
10.2 Gamete banking: sperm, oocytes & ovarian tissue.
10.3 Pancreas islets.
10.4 Hepatocytes.

The activities related to main subjects in tissue banking are proposed by the tutors in order to improve the participants training and learning. The activities are presented and structured by topics at the same time the students are doing each module. This means that when the participants are learning a certain module, during that same period they are doing the activity related to that module. Some of the activities had to be submitted to the tutors before the deadline to be evaluated (activities 1, 2, 3 and 6) whereas some others are forums in which participants have the chance to interact with International tissue banking professionals (activities 4, 5, 7.1, 7.2, 9 and 10). The Activities are guided by professional experts that give their feed-back to the participants and promote the discussion about the subject proposed in the Forum.
Activities:

<table>
<thead>
<tr>
<th>Activity 1.</th>
<th>Presentation – Tutors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity 2.</td>
<td>Guidelines – Esteve Trias</td>
</tr>
<tr>
<td>Activity 3.</td>
<td>Physical Examination – Aurora Navarro</td>
</tr>
<tr>
<td>Activity 4.</td>
<td>Infectious diseases transmission through tissue transplantation – Scott Brubaker</td>
</tr>
<tr>
<td>Activity 6.</td>
<td>Virtual Tissue Bank – Oscar Fariñas / Deirdre Fehily</td>
</tr>
<tr>
<td>Activity 7.1.</td>
<td>Principals of cryopreservation – David Pegg</td>
</tr>
<tr>
<td>Activity 7.2.</td>
<td>Amniotic membrane transplantation – Óscar Gris</td>
</tr>
<tr>
<td>Activity 9.</td>
<td>Skin Banking – Alberto Bolgiani</td>
</tr>
<tr>
<td>Activity 10.</td>
<td>European Quality System in Tissue Banking Project – Martí Manyalich</td>
</tr>
</tbody>
</table>

The participants/tutors ratio in this online course was less then 10:1. Tutors were supported by experts from faculty board and consultants.

Face-to-face Training Course

The face-to-face course took place during 2 days in La Coruña (Spain), on April 21-22, 2006, while students were also taking part in the on-line course. The participants of the course were divided into two groups (clinical and technical staff) according to their educational background, job description and responsibilities in the tissue establishment. However, there were some aspects of the course that were addressed to both groups. This course has been built to put into practice theoretical knowledge, which is not only very useful for processing and procurement technicians, but also for medical directors and quality assurance managers, since with this course, they are able to increase their level of expertise and know-how in many aspects.
The contents of the face-to-face are the following:

- European legislation
- Quality control and quality management in tissue banking
- Sterilisation methods and their validation
- GMP standards for processing environment microbiological sampling
- Donor selection (C)
- Risk assessment and risk management in tissue banking (C)
- Equipment validation and maintenance (C)
- Process validation (C)
- Processing problems, practical approach (C)
- Tissue retrieval (T)
- Tissue processing (T)
- Health and safety in tissue banking (T)

The letters in parenthesis represent Clinicians (C) and Technicians (T). This means that those aspects were only addressed to one or the other. For those aspects in which there is no specification, it means both personnel were trained on that (see Evaluation of the Course section for the final conclusions of the course).

The training of technicians was carried out by putting into practice procurement and processing techniques in pigs; the tissues retrieved and processed included heart valves, pericardium, blood vessels and bone.

24 of the 28 participants were certified with this training course.

b) **Second evaluation of participants’ knowledge**

As mentioned in section 4, participants were asked to fill in a post-evaluation questionnaire after having performed the on-line and the face-to-face courses, where their knowledge gained was evaluated. The results
showed that participants did quite increase their knowledge and expertise by means of these training courses.

- Persons that answered the post-evaluation questionnaire: 21 out of 28
- Average score: 8.9 out of 10

To be able to compare the results rightly, 4 more surveys should have been received (in order to compare 25 pre- to 25 post-evaluation surveys). Nevertheless, we can conclude that the average grade before taking the training model (7.8) is substantially lower than the one achieved after the training (8.9).

c) Final adaptations done in Training Model

As a result of the analysis of the post-evaluation questionnaire and a thorough assessment of the training model by the course attendants, final adaptations have been made to the training model. The evaluation of the training course is described next.

EVALUATION OF THE TRAINING COURSE

A) Participants’ assessment on the face-to-face course:

After the celebration of the face-to-face Course, a Questionnaire of Evaluation of the course was distributed among the people who attended. The questionnaire had 6 parts; three of them were opened questions in which pupils had to give their opinion and, in the other three pupils had to give a note to the proposed questions according to the following scale: 1 – nothing at all adequate; 2 – not very adequate; 3 – adequate; 4 – very adequate.

21 Pupils answered the questionnaire, which is 75% of the people attending. The results have been the following:
1. **Organisation of the Course**

The first point was referred to the “Organisation of the Course”: management, information, support, coordination and attention before and in situ, schedule, didactic material, etc. The average score has been 8.6, which is between adequate and very adequate.

<table>
<thead>
<tr>
<th>Organisation of Course</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Average Score (out of 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of the Course</td>
<td></td>
<td></td>
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<td></td>
<td>9.2</td>
</tr>
<tr>
<td>Information before the Course</td>
<td>7</td>
<td>14</td>
<td></td>
<td></td>
<td>8.2</td>
</tr>
<tr>
<td>Support, attention before the Course</td>
<td>1</td>
<td>10</td>
<td>9</td>
<td></td>
<td>8.3</td>
</tr>
<tr>
<td>Information and Coordination in situ</td>
<td>2</td>
<td>13</td>
<td>9</td>
<td></td>
<td>8.7</td>
</tr>
<tr>
<td>Support, attention in situ</td>
<td>7</td>
<td>14</td>
<td></td>
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<td>9.2</td>
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<tr>
<td>Hotel Trade Installations</td>
<td>2</td>
<td>19</td>
<td></td>
<td></td>
<td>9.8</td>
</tr>
<tr>
<td>Training Installations</td>
<td>8</td>
<td>13</td>
<td></td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Duration</td>
<td>6</td>
<td>12</td>
<td>3</td>
<td></td>
<td>7.1</td>
</tr>
<tr>
<td>Fulfilment of the schedule</td>
<td>4</td>
<td>11</td>
<td>6</td>
<td></td>
<td>7.7</td>
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<tr>
<td>Didactic material</td>
<td>1</td>
<td>11</td>
<td>9</td>
<td></td>
<td>8.4</td>
</tr>
<tr>
<td><strong>Average Score</strong></td>
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<td></td>
<td></td>
<td></td>
<td>8.6</td>
</tr>
</tbody>
</table>

![Organisation of the Course](image)

2. **Contents**

The opinion of the attending people as far as “Contents” are concerned: objectives of the course according to the professional activity, development, methodology, quality, support, participation, integration among theory and
practical classes, etc., was also between adequate and very adequate, with an average score of 8.4.

<table>
<thead>
<tr>
<th>Contents</th>
<th>Theory</th>
<th>Average Score</th>
<th>Practice</th>
<th>Average Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives of the Course according to your professional activity</td>
<td>1 12 8</td>
<td>8.2</td>
<td>2 10 9</td>
<td>8.3</td>
</tr>
<tr>
<td>Interest of the contents of the Course</td>
<td>1 11 9</td>
<td>8.3</td>
<td>10 11</td>
<td>8.8</td>
</tr>
<tr>
<td>Development of the classes</td>
<td>1 2 12 6</td>
<td>7.7</td>
<td>2 11 8</td>
<td>8.2</td>
</tr>
<tr>
<td>Methodology used by teachers</td>
<td>2 7 12</td>
<td>8.7</td>
<td>2 14</td>
<td>8.9</td>
</tr>
<tr>
<td>Quality of Presentations</td>
<td>1 10 10</td>
<td>8.6</td>
<td>2 14</td>
<td>8.9</td>
</tr>
<tr>
<td>Support of the teachers</td>
<td>1 7 13</td>
<td>8.9</td>
<td>1 16</td>
<td>9.3</td>
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<tr>
<td>Your Participation in classes has been</td>
<td>1 13 7</td>
<td>8.2</td>
<td>1 11 9</td>
<td>8.4</td>
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<tr>
<td>Your Motivation has been</td>
<td>1 12 8</td>
<td>8.3</td>
<td>1 12</td>
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**Average Score** 8.4 8.7

| Integration among theory and practical classes | 4 9 8 | 8 |

A few questions were asked about the general thoughts towards the course:
POSITIVE OPINIONS OF THE PARTICIPANTS ABOUT THE COURSE:

- Most of the attendants gave a big importance to the interactive aspect of the course, to have contacts and training with others colleagues from others tissue banks.
- They found interesting the subjects and specific topics and the methodologies used by teachers.
- General organization of the course and hospitality of organizers were also two very remarkable things.

NEGATIVE OPINIONS OF THE PARTICIPANTS ABOUT THE COURSE:

- Most of attendees marked the overbooked and tiring schedule and the necessity of a long course to profit the time, to be able to pay attention to all the sessions and to discuss among attending people.
- Another topic pointed out was the convenience of everybody to do the theory and the practice parts.

PLEASE, GIVE A NOTE TO THIS COURSE (Mark with a X the following scale, from 1: DEFICIENT to 10= EXCELLENT)

<table>
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<th>Average Score</th>
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</tr>
</tbody>
</table>

COMMENTS AND SUGGESTIONS:

- Compare the requirements and the practice in the different countries that attend.
- Give the same programme for everybody.
- Focus in the donor selection part more on the developments in new criteria and problems that arise with the application of certain existing criteria.
- The teachers should be more coordinated to structure the didactic material in a better way.
- Most of attending people pointed that a longer course would be necessary for the proposed schedule.
- Many pupils suggested organizing more courses like this.

Suggestions of the participants on the course

1. Compare the requirements and the practice in the different countries that attend
2. Give the same programme for everybody
3. Focus in the donor selection part more on the developments in new criteria and problems that arise with the application of certain existing criteria: Risk assessment

4. The teachers should be more coordinated to structure the didactic material in a better way

5. Most of attending people pointed that a longer course would be necessary for the proposed schedule

6. Suggested to organize more courses like this

Participants were really enthusiastic with the training. However, language had been sometimes a problem, especially for those not fluent in English. Therefore, the best solution is having simultaneous translation during the training for those countries in which it is needed.

Lesson learnt:

1. The idea of hosting a face-to-face course has been of outmost interest. We learned a lot about how to organize a training course within the European context

2. The evaluation of the course has been good in general terms, although several changes should be introduced

3. Areas of interest are related with the quality systems, the risk assessment and the organizational aspects of facilities’ installation and maintenance

4. Probably the course should be extended both in terms of contents and time. More practical sessions should be added, mainly focused on the risk assessment and the facilities

5. The programme needs to be updated to be adapted to the received suggestions. More coordination between lecturers needs to be organized for further editions

6. The idea of dividing the group in two subgroups (technical and administrative) needs further evaluation, but probably every attendant should follow the whole course. But, in any case, a pre-selection of the attendants is also mandatory in order to adapt the contents to their interest and experience.
B) Participants’ assessment on the on-line course:

At the end of the course, participants were asked to fill in an Assessment Questionnaire in which they should score the different aspects of the course from 1 to 5 (1= poor, 2= average, 3= good, 4= very good, 5= excellent) in order to evaluate it.

23 trainees answered the questionnaire, which is 82% of the course participants. The next sections show the rates obtained out of 10 (converted rates).

1. Course Development

Participants have evaluated each module considering the quality of the contents and their accuracy in the program, as well as the interest regarding their expectations.

<table>
<thead>
<tr>
<th>Course development</th>
<th>Rate</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theoretical modules</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contents</td>
<td>7,7</td>
<td></td>
</tr>
<tr>
<td>Accuracy</td>
<td>7,5</td>
<td></td>
</tr>
<tr>
<td>Interest</td>
<td>7,7</td>
<td>7,6</td>
</tr>
<tr>
<td>Activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contents</td>
<td>7,9</td>
<td></td>
</tr>
<tr>
<td>Accuracy</td>
<td>7,7</td>
<td></td>
</tr>
<tr>
<td>Interest</td>
<td>7,9</td>
<td>7,8</td>
</tr>
</tbody>
</table>

![Course Development Chart]

The chart above illustrates the scores for theoretical modules and activities, with contents, accuracy, interest, and total scores.
2. **Organisation**

The organisation and structure of the on-line training course has been evaluated considering the different sections of the virtual campus.

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Rate</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure of the course</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syllabus</td>
<td>7,4</td>
<td></td>
</tr>
<tr>
<td>Glossary</td>
<td>7,2</td>
<td></td>
</tr>
<tr>
<td>Evaluation system (quiz)</td>
<td>7,2</td>
<td></td>
</tr>
<tr>
<td>Bibliography</td>
<td>7,8</td>
<td>7,4</td>
</tr>
<tr>
<td>Didactical material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Texts</td>
<td>8,2</td>
<td></td>
</tr>
<tr>
<td>Graphics</td>
<td>7,6</td>
<td></td>
</tr>
<tr>
<td>Video-Audio</td>
<td>7,8</td>
<td>7,9</td>
</tr>
</tbody>
</table>
3. Course Staff

The course staff was also evaluated considering the different functions and role during the course development.

<table>
<thead>
<tr>
<th>Course staff</th>
<th>Rate</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timeliness in delivering course instructions and previous materials for the course</td>
<td>6,8</td>
<td></td>
</tr>
<tr>
<td>Virtual community quality (access to forums, chats, discussions, conferences...)</td>
<td>7,0</td>
<td></td>
</tr>
<tr>
<td>Technical infrastructure of the course (access to documents, downloads...)</td>
<td>8,0</td>
<td></td>
</tr>
<tr>
<td>Effectiveness in performing web-based applications</td>
<td>7,6</td>
<td>7,4</td>
</tr>
<tr>
<td>Ability and efficacy in solving pedagogical issues</td>
<td>7,6</td>
<td></td>
</tr>
<tr>
<td>Ongoing feedback provided by tutors</td>
<td>7,2</td>
<td></td>
</tr>
<tr>
<td>Monitoring of personal learning by teaching staff</td>
<td>6,6</td>
<td>7,1</td>
</tr>
<tr>
<td>Efficiency of the online technical assistance</td>
<td>7,6</td>
<td></td>
</tr>
<tr>
<td>Technical expertise of the teaching staff</td>
<td>8,0</td>
<td>7,8</td>
</tr>
</tbody>
</table>
4. **Overall Evaluation**

Finally, participants were asked to evaluate the overall course and its applicability to their job. The rates obtained indicate that the course is a very good tool to train health professionals involved in the Tissue Banking activities.

<table>
<thead>
<tr>
<th>Global evaluation</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicability to my job</td>
<td>8,2</td>
</tr>
<tr>
<td>Please, assess the overall course</td>
<td>7,6</td>
</tr>
</tbody>
</table>

**Lesson learnt:**

1. Performing an online course has been of outmost interest. It must be performed before the face-to-face course so that all the necessary theoretical information is acquired in advance.

2. Apart from the theoretical modules, it is important and motivating for the participants to include a series of activities in order to obtain practical knowledge.

3. It is important to provide all the necessary tools, including didactic material and communication tools, in order to increase the knowledge of participants.

4. The coordination of the course is a very important issue to keep in mind when developing such a course. The timeliness in delivering the material before the course begins should be improved. Likewise, special attention must be paid to the monitoring of the learning by the teaching staff.
5. The participants find the knowledge acquired through the online course very applicable to their jobs and functions.

Final Conclusions for the Training Course

1. With the improvement made on the training course taking into account the suggestions from participants, the model of training created, structured into one online and one face-to-face course, aims to be a very adequate method of qualifying personnel and finally certifying their knowledge by means of European certification.
2. The combination of on-line and face-to-face courses is very adequate.
3. There are several main points of the regulation’s application which deserve more attention and time during the training course: Quality systems, Biovigilance, GMPs, Risk Assessment. Design of the units, validation.
4. Practices and practical cases in the face-to-face course should be performed in small groups of people (3-4 people), as this will increase the real practical participation of attendants, thus improving their know-how.
5. The same schedule should be organized for all participants in the face-to-face course (all attendants should be trained in the entire tissue banking process, including the coordination and donation part, as well as the procurement and processing parts, so that all staff are aware of the entire process and have knowledge of all the aspects.

Transferability of WG3 results

The objective of WG3, which has been to develop a model for training tissue banking personnel, has been achieved. We believe this training model to be very adequate for the instruction of TE staff. It comprises all the necessary information in order to guarantee their competence. Member states could adopt (and/or adapt) this training model to their tissue bank and their needs. We believe that it would be interesting for the EC to maintain this training model after the project finalisation. The training model needs to be updated as new concepts and information appear. For this purpose, perhaps there should be an organisation that takes on these tasks and makes the model to go on in the future.
Incidences and Deviations regarding the achievement of the objectives:

1. Letter from European Commission
   During this last working period, the project promoter has received two letters from the European Commission (September and November 2006) in which a few things were asked from all working groups. As concerns WG3, the Commission had a few questions, which are shown below:
   - Which are the specific objectives that have been set for the students.
   - What are the specific objectives that have been set for the students.
   - How does the project see the selection and qualification of teachers.

   The Commission also asked for a copy of the pre-evaluation of knowledge test and a copy of the full course in English. A reply was sent to the EC on September 2006 in which all of the above questions and missing documents were provided.

2. Place where face-to-face course was held
   Initially, the face-to-face course was meant to be held in Barcelona. However, it was decided during the second working period that the course should take place in La Coruña instead, in the Hospital Universitario Juan Canalejo premises. The reason for doing such a change is that the premises of the aforementioned hospital were considered to be better for the different aspects of the course.

3. Execution of other activities

   1. Participation in the “Guide of Recommendations” concerning the following Key Points:
      - Donor evaluation
      - Processing, preservation, packaging and storage of tissues and cells in TEs
      - Training of personnel organisation
3. Answer all the requirements from the EC and sent them to the leader of the project, which was then sent to the EC (in September 2006).
4. Attendance at the final meeting held in Barcelona on February 2007. Presentation of WG3 results and conclusions on the training model (please see WG3 Presentation: Annex D5)
   – Blanca Miranda: ONT, Spain
5. Invitation to the meeting of the Competent Authorities of Tissues and Cells in Brussels on the 8th of February 2007 in order to present the project training model.
   o Attendants: Aurora Navarro, Blanca Miranda and Martí Manyalich.
   o 4 dossiers presenting the training model were passed on to the participants during the meeting

4. Future Activities
   a) Dissemination of the Sanco-EQSTB Project, the Guide of Recommendations and the Guide for Auditing Tissue Establishments in diverse local, national and international meetings.
Table of Contents

1. Introduction WG4
   - Group members
   - Tasks
2. Objectives and Results achieved
   - Design the European Auditing Model of tissue establishments
     - 2nd working period
       1. Auditor profile
       2. Audit methodology
       3. Distribution of tasks
     - last working period
       1. Auditor profile
       2. Audit methodology
       3. Guide for Auditing Tissue Establishments
   - Pilot audits
     - 2nd working period
     - last working period
   - Transferability of WG4 results
   - Incidences and Deviations
3. Execution of other activities
4. Future Activities
1. Introduction

Group members:
Theo de By, BIS Foundation, The Netherlands
Esteve Trias, Transplant Services Foundation, Spain
Clara Fernández, Transplant Services Foundation, Spain.

Tasks:
The main objective of this working group was to design a European Tissue Establishment Auditing Model, based on the results obtained from working groups 1, 2 and 3 regarding the tissue banking quality and safety key points, the primary registry data and the training model, as well as on the thorough analysis carried out on the European Directives on tissues and cells: 2004/23/EC, 2006/17/EC and 2006/86/EC. A preliminary audit model was defined and, to further improve and validate the model, 4 pilot audits were performed. As a result, the final audit model has been obtained in the form of a guide, the Guide for Auditing Tissue Establishments (further as Guide).

This Guide includes:
- an introductory section describing the background, the purpose and the structure and contents of the Guide
- the regulatory framework enveloping the current legislation on tissue banking in Europe
- a glossary of terms and abbreviations
- the audit procedure, including the outset, submission of documentation, audit, post audit, and audit result
- the audit manual, structured according to each main keypoint/standard, including auditor guidance and a set of guiding questions for that standard
- an Audit Report form
- a “Site Master File” – a document to be filled in by the applicant tissue establishment providing detailed information about the bank, and to be sent to auditors prior to the audit

Another task of this working group has been to develop a transferability report describing the applicability of the audit model at a European level once the EQSTB project finalises.

2. Objectives and results achievement

The following objectives of this working group have been achieved:

1. Design a European Auditing Model of tissue establishments based on EU Directives on tissues and cells, and on the tissue banking quality and safety key points, the common nomenclature data registry system and the specialised training model
2. Perform 4 pilot audits using the audit model to improve and validate the model
3. Develop a transferability report describing the applicability of the model at European level

It has been at the end of the second working period and beginning of the last that the working groups 1 to 3 have obtained results and have began drawing conclusions from its objectives. For this reason, WG4 has done most of its activity during the last period, after being able to gather together the results from the other working groups.

1. Design the European Auditing Model of tissue establishments

Second Working Period
During the second working period, a preliminary design of the European auditing model was developed. It was decided that the audit model would be based on the tissue banking quality and safety key points detected by working group 1, as
well as on the common registry data defined by working group 2 and taking into account the specialised training model produced by working group 3. On February 2006, the European Commission produced the first technical annex to Directive 2004/23/EC, which is 2006/17/EC. Both of these Directives were carefully studied and they became, together with the results from WGs 1-3, the grounds on which the Audit Guide would be based.

Auditors’ Profile:
During the period from May 2005 to May 2006, a preliminary definition of the auditors’ profile was obtained. During the second meeting held in Bologna, this was presented: the audit should be carried out by a team of 2 persons, from different countries as those of the tissue establishments to be audited. This team should have broad knowledge on the following areas: donor selection criteria, quality systems and GMPs (Good Manufacturing Practices), IT systems, regulations, personnel training and competence, and traceability and adverse outcomes. One of the team members should have a senior professional level, and the other one at least 2 years of experience in tissue establishments. Both of them should of course have previous training and experience in auditing. The proposal was the following:

- Tissue Bank Expert I (general manager, medical director or quality manager)
- Tissue Bank Expert II (someone from a different region working in a different field of tissue banking, who has knowledge on the areas mentioned above and has expertise in tissue establishments including tissue processing)

Audit Methodology:
Another task that was achieved during the second working period was to obtain an initial description of the audit methodology. A guideline was agreed for conducting an audit, which consisted of the set of documents to review and the key areas of activity to control. These documents and key areas were the quality and safety key points, and they should be reviewed to see whether the establishment fulfilled them.
It was decided to structure the audit as follows:

a) Documentation required before audit
b) Audit
c) Evaluation
d) TE feedback

a) Documentation required before audit
It was decided that the documentation that the applicant centre should send to the auditors before the audit is:

− Identification of key individuals and their responsibilities
− A list of tissues procured, processed and supplied, and level of activity.
− A description of the Quality System in operation
− The annual report
− An organisational chart
− A site plan

b) Audit itself
The audit should last 1 or 2 days, depending on the range and volume of activity of the tissue establishment. Several procedures should be observed in action. A preliminary audit checklist/self assessment questionnaire was obtained, which was meant to be used by the auditor during the audit.

c) Evaluation
It was decided that once the audit was finished, the auditors should summon a meeting to review and agree findings and classify any non-conformities. A verbal report on findings would be provided to key staff members at the end of the audit, followed by a written report to be developed during the next 2 to 4 weeks. The non-conformities were also numbered and defined (critical, major, minor and comment non-conformities).

d) TE feedback
It was decided that the audited tissue establishments should prepare and submit an action plan to the auditor team no later than 1 month after the audit (if
considered necessary). Certification of the tissue bank would then be recommended if applicable.

Distribution of Tasks:
During the second working period, the different tasks to be carried out were distributed among the WG4 partners (TSF, BIS and NLTB). The quality and safety key points regarding the standards, registry and training were structured the way shown below. The decision of making a partner responsible for a specific section (shown below) was taken on the basis of the partners’ background and expertise in the field:

- General Policies – BIS
- Tissue Donation – TSF
- Tissue Procurement – TSF
- Tissue Processing – NLTB
- Tissue Storage – NLTB
- Tissue Distribution and reception – BIS

The idea was to audit these six areas, and to use this structure to develop the *Guide for Auditing Tissue Establishments*. By the end of the second working period, a preliminary draft was obtained from each WG4 partner.

**Last Working Period**

During the period from May 2006 to May 2007, the final *Guide for Auditing* has been developed. A few changes were made to the audit model, mainly on the auditors’ profile and the audit methodology. Also, more auditor guidance was provided for each standard, since it was detected that this part of the guide is very much of use for the auditor and it was not very detailed. As has been mentioned earlier, the Guide takes much into account the results and conclusions drawn from the other working groups, as well as the European Directives on tissues and cells. It was on October 2006 that the European Commission produced the second technical annex to the 2004/23/EC Directive, D. 2006/86/EC. This annex has been an extremely important and helpful
document for WG4, since now we have been able to develop a complete Audit Guide for TE\textsuperscript{s} to fulfil the requirements of the EU.

\begin{itemize}
  \item \textbf{Auditor Profile}
  \end{itemize}

As a result of some of the pilot audits, some changes were made as to what the auditors’ profile should be. These modifications were presented at the final meeting in Barcelona in February 2007. It was concurred that there should be 3 auditors instead of 2. The final auditor profile that was agreed shown below:

- Expert I: person with experience in the field of Quality and quality systems, with broad knowledge and expertise of the ISO and GMP systems.
- Expert II: person with a health-organisation background, with knowledge and experience in the donation and transplant coordination processes.
- Expert III: person with much experience in a tissue establishment, who has wide knowledge of the technical processes carried out in the TE (e.g. tissue procurement, processing...).

Of course, all auditors should have experience as such and should have received previous training on auditing. During the audits, it was seen that, in some cases, depending on the country where the audit takes place, and if none of the auditors speak the language of the country in question, it might be necessary to have an interpreter with the team in order to verify documentation and facilitate the entire process.

\begin{itemize}
  \item \textbf{Audit Methodology}
  \end{itemize}

During this last working period, the final procedure to carry out an audit has been decided. It is determined by an evaluation of the documentation provided by the applicant tissue establishment and by the on-site audit.

The audit methodology should consist of the following steps:

\begin{itemize}
  \item a) Outset
  \item b) Submission of Documents
  \item c) Audit
  \end{itemize}
d) Post Audit
e) Audit Result

Next is a detailed description of the aforementioned steps, as they have been described in the *Guide for Auditing Tissue Establishments*.

- **Outset**
The audit lead assessor should announce to the auditees that an audit is going to take place, and propose a date or timeframe for it. The purpose of the audit also needs to be stated (for instance for the EU; on behalf of the national inspector; a second party, etc. The lead assessor will indicate who the auditors are, and must give a short explanation of the procedure and the personnel who are expected to attend (quality management, director, and/or others).

- **Submission of Documents**
The applicant centre should submit the pre-audit documentation approximately 3 weeks prior to the expected audit date. This way, the appointed auditors will have enough time to review the files. For this matter, a document has been elaborated which comprises all the information about the TE that the auditors need to know before the audit: the so-called Site Master File (see Annex Q1 to review the document).

The documentation to be submitted should be:

- ✔ Site Master File duly completed, including:
  - Identification of key individuals and their responsibilities
  - Premises, equipment, etc.
  - Tissue activities: tissues procured, processed and supplied, and level of activity
  - Description of the Quality system in operation
  - Organisational chart
  - Site plan
- ✔ Quality Manual where possible (including list of SOPs)
- **Audit**

The audit will be arranged between the auditors and the applicant centre. The time necessary for the on-site audit is decided in advance by all involved. Depending on the size of the tissue establishment and the level of activity, 2 or 3 days might be appropriate. The audit is performed by persons qualified by training and experience in tissue banking activities, who have adequate technical training and expertise as auditors, and have knowledge of the European Directives. It is fundamental that an independent and objective attitude is maintained by the auditors and the planning and performance of the audit is carried out professionally. The auditors are chosen in such a way as to guarantee that the team has the required knowledge and experience to adequately examine the applicant programme. If any conflict of interest is perceived, applicants are entitled to call for a change in auditors prior to the audit.

The audit focuses on the defined core requirements regarding tissue donation, procurement, processing, storage and distribution, as required by the European Directives.

- **Post Audit**

Following the audit, the team makes up the audit report based on its own observations, and taking into account those of other auditors if applicable. This report will state whether the tissue banking activities are carried out in accordance with the requirements of the Directive. The team will review and agree on findings and will classify any non-conformity that might appear.

The Audit Report is shown next:
AUDIT REPORT FORM

DATE:

AUDITED ORGANISATION
Name:
Address:
Location:
Representative:

AUDITEES
NAME: DEPARTMENT / RESPONSIBILITY

AUDITORS
NAME: ENTITY / RESPONSABILITY:

OBJECTIVES AND SCOPE OF THE AUDIT

SUMMARY OF REPORT
1. PARTS AUDITED

<table>
<thead>
<tr>
<th>ELEMENT</th>
<th>Parts audited</th>
<th>NC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality management system, Quality strategy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documentation requirements - (quality manual, SOPs, guidelines, records)</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Management commitment</td>
<td>☐</td>
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<tr>
<td>Customer focus</td>
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<tr>
<td>Quality policy</td>
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<tr>
<td>Responsibilities, authority and communication</td>
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<tr>
<td>Quality management review</td>
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<tr>
<td>Personnel competency and training</td>
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<tr>
<td>Infrastructure</td>
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<tr>
<td>Supporting services and agreements</td>
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<td>☐</td>
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<tr>
<td>Data protection and anonymity</td>
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<td>☐</td>
</tr>
<tr>
<td>Product realization - general concepts</td>
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<tr>
<td>Identification and traceability</td>
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<tr>
<td>Validation of processes</td>
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<tr>
<td>Equipment suitability</td>
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<tr>
<td>Environmental conditions of production area</td>
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<tr>
<td>Pooling and cross-contamination</td>
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<tr>
<td>Control of monitoring and measuring devices - calibration, ...</td>
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<td>☐</td>
</tr>
<tr>
<td>Packaging and labelling of product</td>
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<tr>
<td>Tissue Donation</td>
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<tr>
<td>Donor coding</td>
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<td>☐</td>
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<tr>
<td>Donor selection and evaluation</td>
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<tr>
<td>Donor documentation</td>
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<tr>
<td>Donor testing</td>
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<tr>
<td>Tissue Procurement</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Method and conditions</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Retrieval documentation</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Transport to processing centre</td>
<td>☐</td>
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<tr>
<td>Tissue Processing</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Processing conditions</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Microbiological testing of final tissue</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Tissue Preservation and Storage</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Conditions</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Quarantine</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Tissue release - authority...</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Tissue Distribution</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Transportation</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Reception policies at end user</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Waiting lists</td>
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<td>☐</td>
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## 2. DOCUMENTATION REVIEWED

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### Additional Comments

### CRITICAL NON-CONFORMITIES

1.

2.

3.

### MAJOR NON-CONFORMITIES

### MINOR NON-CONFORMITIES

### OBSERVATIONS

### AUDIT SUMMARY

### STRONG POINTS

### TIMESCALE FOR CORRECTIVE ACTIONS
In the list of parts audited, auditors should tick the areas audited and the non-conformities that have appeared.

A verbal report on findings will be provided to key staff members of the tissue establishment at the end of the audit. The written audit report should be sent to the TE within two weeks, and it will lay out the non-conformities and provide a timescale of corrective actions (by which the non-conformities should be corrected) so that proper audit closure can occur in a timely fashion. For EU Directive requirements, it will be necessary to achieve 100% of the standard conditions; however, in some other areas, a lower percentage might still be considered acceptable (non-adherence to recommendations and voluntary standards will not be subject to non-conformity judgement).

Facilities are given a reasonable period of time to correct the noted non-conformities. It is important to reach agreement about the recommendations for change and improvement. The facility should come up with a corrective action plan stating who is named responsible for each amendment and the timescale for its completion.

- Audit Result
After drawing up the audit report and giving the TE some time to correct the non-conformities, the auditors should request “evidence” to show that the changes and improvements have been made. This evidence shall be submitted to the audit team to confirm that the TE now meets the requirements of the standards.
However, depending on the number and severity of the non-conformities noted, reconsideration of the additional documentation may be required and/or a decisive on-site re-audit may be regarded as necessary.

This stage is critical as it shows whether the outcome of the audit process has been completed. The results of the good audit should be disseminated locally and, where possible, nationally (for example via professional journals and transplant organisations).

➢ Guide for Auditing Tissue Establishments:
As mentioned earlier, it has been during this last working period that WG4 has finally achieved its objective: to develop the audit model and elaborate the *Guide for Auditing Tissue Establishments*.

As is described at the beginning of this section (section 1), at the end of the second working period, WG4 began gathering preliminary results and conclusions from the other working groups. During the last working period, all the Directives on tissues and cells were available, and this made it possible to develop an audit guide which took into account all the key aspects in tissue banking (Directives 2004/32/EC, 2006/17/EC and 2006/86/EC).

As a result of the pilot audits and observations (described in section 2), the comments from all project partners, and suggestions from EC members and the two external auditors of the project, the *Guide for Auditing* has been obtained (please see the *Guide for Auditing Tissue Establishments* document). The Dissemination section of the promoter part of this final report explains in detail the process of design and editing of the Guide.

This Guide has been elaborated in order to provide tissue banking experts with the necessary tool to audit tissue establishments against the quality and safety key points and the EU Directives. The Guide has been elaborated in such a way which allows the TE to be audited by external auditors as well as by the internal
TE staff. It is meant for auditing TE against the current EU Directives and, as mentioned above, it is intended for two different groups of individuals:

1. For auditors

The Guide will be very helpful for auditors to guide them through an audit, since it contains all the *standards*, or quality and safety key requirements, related to tissue banking; *guidance* on what to search for and review while auditing, and a *checklist* consisting of a set of questions relating to each standard with writing space for the auditor to note down any observations and comments associated with specific items.

2. For tissue establishments

The Guide can also be used by TEs to give them an idea of what is expected of them and what auditors will be looking for. The checklist with the sets of questions can be utilised as a self-assessment tool so that the TE can “audit” itself.

The checklist mentioned above will be very useful for tissue establishments to audit themselves and verify their compliance to EU Directives. For auditors, what will very helpful and practical are the standards and the guidance; the checklist can be used as an ‘aide-memoir’ at certain stages during the audit (or at its end) whenever the auditor wants to go into more detail for a specific key point.

Next is the Table of Contents of the *Guide for Auditing TE*:

**TABLE OF CONTENTS**

1. Introduction
   1.1. Background
   1.2. Purpose and Application
   1.3. Structure, Contents and Approach
2. Regulatory Framework
3. Definitions and abbreviations
   3.1. Definitions
   3.2. Abbreviations
4. Audit Procedure
   4.1. Outset
   4.2. Document Submission
   4.3. Audit
   4.4. Post-audit
   4.5. Audit decision
5. Audit Manual

Part A: General Policies
- A.0 General Considerations for auditors
- A.1 Legal and Regulatory Framework
- A.2 Standard Operating Procedures
- A.3 Specific Aspects of the Quality System
- A.4 Data Protection and Anonymity
- A.5 Traceability
- A.6 Personnel Training and Qualification
- A.7 Health and Safety of Staff; Compliance with legal requirements
- A.8 Packaging and Labelling
- A.9 Records and Registers

Part B: Tissue Donation
- B.1 Donor Selection and Evaluation
- B.2 Donor Coding
- B.3 Donor Testing
- B.4 Donor Documentation

Part C: Tissue Procurement
- C.1 General Principles
- C.2 Retrieval Conditions
- C.3 Retrieval Documentation
- C.4 Transportation to TE

Part D: Tissue Processing
- D.1 General Principles
- D.2 Equipment Suitability, Sterility and Traceability
- D.3 Environmental Controls
- D.4 Traceability of tissue through processing
- D.5 Microbiological testing of final tissue
- D.6 Adverse Event Management

Part E: Tissue Storage
- E.1 General Principles
- E.2 Storage conditions
- E.3 Tissue release

Part F: Tissue Distribution
- F.1 General Principles
- F.2 Transportation
- F.3 Reception policies at the End User
- F.4 Adverse Event Monitoring and Recall
- F.5 Waiting lists and Import/Export Policies

6. Shortcut to audit guidance parts A to F
7. Audit Report
8. Annexes

Annex 1: 2006/86/EC Annex VI, Article 9
Annex 2: Site Master File

As can be seen in the aforementioned table of contents, the Audit Manual is the part of the Guide which comprises the quality and safety core requirements of tissue banking. Each subpart of the manual is structured as follows:

- Standard / Key Point
- Auditor guidance
- Checklist / questions

As an example, subpart E.3: Tissue Release is shown below:
E.3 TISSUE RELEASE

STANDARD:
There must be a safe system for authorising and executing the transfer of tissues from quarantine to available for distribution. Expiry Dates must be established for all tissues released. Release for transplantation must be done by the responsible medical officer and quality assurance officer. There must be SOPs for the release and exceptional release of tissue for transplantation.

AUDIT GUIDANCE:
Ask the person responsible for tissue release to show you how the transfer of tissues in quarantine to available for distribution is made. Verify that expiry dates are always established for all tissues released. Ask for and review the SOP of release and exceptional release of tissue for transplantation.

CHECKLIST: Tissue Release
1. Safe system for authorising and executing the transfer of tissues from quarantine to available for distribution:
   Are there:
   - SOP for release in place                                   Yes  No  N/A
   - SOP for transfer to clinical use                           Yes  No  N/A
   - Release includes medical, production and independent quality approval Yes  No  N/A
   - Mechanism for release is approved by the Responsible Person Yes  No  N/A

2. Expiry Dates established for all tissues released
   2.1 Expiry date defined:
   - Expiry dates are validated to maintain tissues fit for purpose Yes  No  N/A
   - Expiry times are defined in policy                         Yes  No  N/A
   2.2 Stock control:
   - Inventory is up-to-date                                  Yes  No  N/A
   - Stock is rotated to prevent wastage                       Yes  No  N/A
   - Stock control policy in place                             Yes  No  N/A
   - Stock control manages donation activity to maximise use    Yes  No  N/A

Auditor Comments: 

The idea is that the auditors have knowledge of the standards, and use the guidance provided to ask the auditees for the necessary documentation, process review, etc. For this reason, and to make the auditors' work easygoing, all the auditor guidance provided has also been placed together in one part of the Guide (section 6 of the Guide).

2. Pilot audits

Second Working Period
During the second working period, it was agreed that the 4 pilot audits to be performed should be the following:

- North London Tissue Bank (NLTB) (Liverpool, England)
- Transplant Services Foundation (TSF) (Barcelona, Spain)
- East European country tissue bank: National Centre for Tissue and Cell Banking (NCTCB), Medical University Warsaw (Warsaw, Poland)
- Tissue bank with recent audit report (ISO, national inspection,...) to compare findings: Banca del Tessuto Muscolo-scheletrico, Istituti Ortopedici Rizzoli (BTM-IOR) (Bologna, Italy)

**Last Working Period**

During this last working period, the four pilot audits have taken place, between July 2006 and January 2007. For each audit, notes were taken in order to develop written reports on the audits. We have elaborated so-called ‘audit diaries’ for each audit, in which how each audit went is explained in detail. After the first audit took place (NLTB), the need for having an Audit Report form was detected and hence, an audit report was elaborated. This form was then used in the subsequent 3 audits and as a result, 3 audit reports, one for each audit, were developed and sent to the audited tissue establishments.

It was decided that the audits should be performed in the following order:
1. NLTB
2. NCTCB
3. BTM-IOR
4. TSF
Given that the persons carrying out the audits are the WG4 partners, it was agreed that it would be helpful to perform the first and last audits “at home”, since this would make the process more easygoing in the first place and it would help to detect the real needs in order to create an adequate audit model. NLTB was chosen because of its years in the field, its wide expertise, and its possession of clean room facilities. TSF was selected due to the fact that it is a multi-tissue bank, and it was thought that it would be interesting to audit a tissue establishment with such characteristics. The second bank to be audited, NCTCB, was chosen as it is an east-European establishment, with a background of less experience in the field, especially concerning the regulatory framework in Europe. Finally, BTM-IOR, a musculoskeletal tissue bank, was chosen because it would be interesting to audit an establishment audited/inspected many times at a national level and which has recently received national certification.

Below is a detailed explanation of each one of the four audits that took place between July 2006 and January 2007:

1. **North London Tissue Bank, National Blood Service**
   Date: July 5\textsuperscript{th}, 2006
   Place: Liverpool, England
   Audit diary: Annex Q2

   The first audit that took place was at the National Blood Service in England, more concretely at the North London Tissue Bank in Liverpool. Stefan Poniatowski, who is a member of this working group, was the auditee, and Theo de By and Esteve Trias were the auditors.
The bank that was being audited is blood-institution related organisation and multi-tissue bank. It was seen that NLTB has a tight network of SOPs and a quality system that is organised at a national level.

During this audit, the auditors had a too-optimistic time frame and failed to have a proper framework for the audit. Likewise, the Site Master File had not yet been thought of and developed. No documentation was requested nor obtained from the tissue establishment before the audit took place. However, after the audit was held, the need to have information about the tissue bank before the audit was seen to be an essential tool to carry out the audit successfully. As a result (after the audit took place), the Site Master File was developed, which includes all the information that is necessary to know before the audit is held in order to make the audit easygoing. Stefan Poniatowski filled in the site master file. For the next audits, the site master file was sent to the audited tissue banks in advance and received back on time.

At this point, no audit report form had yet been thought of; the methodology used during the audit was the following: the auditors took notes while speaking to the auditees and reviewing documentation. After the audit, all auditors’ notes were put together and the so-called ‘audit diary’ was developed. This document contained a detailed explanation of how the audit went as well as comments, suggestions and other key information for the auditees to be aware of.

It was some time after this audit took place (end of October) that the European Commission finally published the last technical annex of the Directive on tissues and cells (2006/86/EC). This Directive was very helpful to improve the Guide for Auditing, since it provided recommendations regarding traceability requirements, SAR/E notification, and other requirements on coding, processing, preservation, storage and distribution of tissues and cells.

2. National Centre for Tissue and Cell Banking
The second audit that took place was at the National Centre for Tissue and Cell Banking, at Warsaw. Due to professional reasons, Esteve Trias was not able to assist to this audit and, on his behalf, Aurora Navarro and Clara Fernández attended as auditor and support respectively, together with Stefan Poniatowski and Theo de By as auditors. The auditees in this case were Izabela Uhrynowska, Artur Kaminski, Martyna Tada and Joanna Marowska.

This establishment is also a multi-tissue bank which was at the time in transition to its new premises. There was no written evidence of a quality system, although there was seen to be a good knowledge of quality in general, with different protocols and instructions present.

As is mentioned before, the auditors developed a Site Master File right after the Liverpool audit, which was sent to NCTCB in advance and was filled in by the auditees before the audit. The information provided in the master file was very helpful for the auditors because they were able to have an idea of the organisational structure and activity of the bank before they arrived at Warsaw; this allowed them to be much more prepared to audit the centre.

At this point in the working period, the auditors had developed a quite good draft of the *Guide for Auditing Tissue Establishments* (version 5). Many keypoints/standards were described, and some audit guidance as well as the questions on that standard were provided. With this document, many aspects of tissue banking auditing were covered and it was quite useful for the auditors to have this document in hand because they were able to have all key aspects in mind and structure the audit more easily. As in the previous
Audit, notes were taken by the auditors and once the audit was finished and the auditors were back at their home countries, these were ensembled and the audit diary was obtained.

Also at this point, the auditors become aware of the limit of the project in terms of follow-up necessity. It is decided that it was crucial to elaborate an audit report form in which all the key findings, non-conformities and a timescale for corrective actions could be noted down and communicated to the auditees. However, it is seen that due to the timeframe of the project, no follow-up of the corrective actions can be achieved during the project life. Once the audit report is finalised, it is sent to Warsaw together with the audit diary.

It is due to this second audit that the definitions of the non-conformities are sharpened and final consensus is agreed shortly after this audit. No longer would there be 4 non-conformities, but 3:

- **Critical non-conformity**: if it poses an immediate and serious threat to the safety of a donor, recipient, or staff member
- **Major non-conformity**: If it poses a potential or indirect threat to the safety of a donor, recipient or staff member
- **Minor non-conformity**: if it poses a minimal risk

The ‘*comment non-conformity*’ that was initially defined during the Bologna meeting does not exist anymore; instead, another category has been added which is not considered as non-conformity but as a mere remark:

- **Observation**: if it poses a theoretical or debatable risk to a donor, recipient or staff member

This is due to the fact that it cannot be considered as non-conformity, but it is still considered important to transmit this remark to the tissue establishment as it can contribute to an improvement in the functionality of the establishment.
3. **Banca del Tessuto Muscolo-scheletrico, Istituti Ortopedici Rizzoli**

   Date: December 11-12\textsuperscript{th}, 2006  
   Place: Bologna, Italy  
   Audit diary: Annex Q5  
   Audit report: Annex Q6

   The third audit is held in Bologna at the Banca del Tessuto Muscolo-scheletrico of Istituti Ortopedici Rizzoli. The auditors were Stefan Poniatowski, Theo de By and Esteve Trias, and the auditees Pier Maria Fornasari, Allessandra Basso, Teresa Venezian and Livia Rosetti.

   BMT-IOR is a musculoskeletal-tissue bank which has received previous certifications by different entities. This bank has clean-room facilities and it is GMP operational, with a tightly organised quality system in place.

   During this audit it was seen that it would be very useful for auditors to have easy access to all the *guidance* for auditors; instead of going standard by standard to see each *guidance*, it is quite handy to place these all together somewhere in the document, for example at the end of the Guide. It was decided to leave each *guidance* next to its standard, and also, to put it all together at the end so that auditors can have quick access to all the suggestions.

   At this audit, the auditors were challenged to test their methods; they had much improved their scheduling and reporting, and could fine tune the Site Master File with the draft of the *Guide for Auditing* that was being used (version 5). Both the audit diary and the audit report were developed and sent to Bologna, providing a timescale for the corrective actions to be done.

4. **Transplant Services Foundation**

   Date: January 31\textsuperscript{st} – February 2\textsuperscript{nd} 2007  
   Place: Barcelona, Spain
The 4th and last audit took place in Barcelona, at the Transplant Services Foundation in January. Esteve Trias was the auditee, whereas Theo de By and Stefan Poniatowski were the auditors. TSF is a multi-tissue bank which was in transition to its new facilities at Sant Boi. It is striving for GMPs and it has a complete quality system in place.

During this audit, the auditors practised their learning experience acquired during the previous 3 audits. They produced a very complete standard audit report within a short time frame, which was more complete and efficient than the previous version. The Audit Report form is shown on page 106.

An observer of the European Commission, Thomas Brégeon, was invited to assist to this audit and obtain knowledge of the EQSTB project. He was present during the entire audit, and he provided useful comments and suggestions that were taken into account to develop the final Guide for Auditing Tissue Establishments as well as the final Guide of Recommendations from WG1.

Between the 3rd and the 4th audits, the Guide for Auditing was improved; the version used during the audit at TSF was version 8.

As mentioned in section 1, after all the pilot audits took place, the Guide for Auditing was improved due to the suggestions that arose during the final meeting held in Barcelona, where all the project partners contributed to the Guide with their comments and ideas. Likewise, during the final technical audit of the project that occurred in April-May, the external auditors provided us with some comments that were taken into account to further improve the Guide (especially regarding the introduction of the Guide). These suggestions can be seen at the technical audit reports developed by the auditors (annexes
J1 and J2). The final *Guide for Auditing* was produced and published in May 2007.

3. Transferability report

In order to transfer and apply the audit model at a European level after the project finalises, the members of WG4 consider that the *Guide for Auditing* should be maintained and incorporated in a professional audit scheme, which is not currently in existence in Europe. Initially, it was thought that the transferability and application of the Audit model could be made in two different ways:

1. Act as an independent auditor organisation. This organisation would create a group of experts in tissue bank auditing, with broad know-how and experience in these matters, as a result of the training derived from the TE Audit Guide. Different national organisations throughout Europe could subcontract the services of this organisation to audit tissue establishments in their country. By doing so, they would have the possibility to obtain certification and therefore comply with the EC Directives’ quality and safety requirements in tissue banking.

2. The European Union could officialise this audit model. Based on this model, a group of skilled auditors would be created, for example by the EATB. This association could become the one to regulate audits of TEs throughout Europe. Being audited through this model would guarantee achievement of compliance with both the EATB standards and the requirements of the European Directive. Member States would recognise the expertise of the auditors. This model could be integrated in the obligatory inspections of TE.

During the final meeting held in Barcelona in February 2007, this issue was brought to discussion so that all project partners could give their thoughts and
suggestions on the matter. After commenting the need to have maintenance and a continuous update of the *Guide for Auditing* once the project is finished so that it can be transferred European-wide, and after discussing what the best solution would be, it was agreed that the best thing to do would be to do a mix of the above options: to create an independent body of auditors, and continuously update the *Guide for Auditing*, a task which could be undertaken by the EATB. This organisation could provide this tool to its members, enabling them to organise audits between themselves at their own cost. Perhaps another entity could provide financial support for the performance of tissue establishment audits following this Guide in new Member State tissue banks to help them verify compliance with the Directives and to identify priorities for procedural changes.

Audits of this type carried out by colleagues in the same field but from different Member States and following the Audit Guide developed, could make a major contribution to accelerating progress towards common standards of practice in compliance with the EU Directives. An audit of this type would provide excellent preparation for a tissue establishment before it receives a Competent Authority inspection.

**Incidences and deviations regarding the achievement of the objectives:**

1. During the Bologna meeting on November 2005, it was decided that the terminology (regarding the accreditation) should be reconsidered. The term “accreditation” was changed to the term “audit” during the second working period, because it was seen that the latter applies better to the objectives of this working group.

<An audit is an evaluation of an organisation, system, process, or product. It is performed by a competent, objective, and unbiased person or persons, known as auditors. The purpose is to verify that the subject of the audit was completed or operates according to approved and accepted standards, statutes, regulations, or practices. It also evaluates controls to determine if conformance will continue (evaluate conformance now and into the future).
The key component of clinical audit is that performance is reviewed to ensure that what should be done is being done, and if not it provides a framework to enable improvements to be made.

2. Another decision was made regarding the study of the Rate of Implementation of the European Directives in the different tissue establishments involved in this project. WG1, who was in charge of doing this task, provided WG4 with a questionnaire to analyse this rate. WG4 sent this questionnaire to all project partners for its completion, and received them back in order to compile all the results and do a first analysis of the situation (final conclusions drawn by WG1). It was seen that the best time to examine this implementation rate would be during the pilot audits, since special attention could be paid then. Once the audits finished and WG4 compiled and analysed the results, WG1 provided the final conclusions, which were presented during the final meeting held in Barcelona in February 2007.

3. Execution of other activities

1. Participation in WG2 – Registry
Some partners of WG4 (TSF and BIS) participated in WG2 as regards to the prototype of the registry for bone banks: fill-in of registry database with frozen bone data.
Also, it has participated on the modifications of product list for the Registry: addition of new products (and new options) that were not considered in the registry and modification of some terminology (May 2006).

2. Participation in the Guide of Recommendations concerning the following Key Points:
   - Donor evaluation
   - Data protection
   - Environmental conditions
3. Answer all the requirements from the EC and sent them to the leader of the project, which was then sent to the EC (in September 2006).

4. Attendance at the final meeting held in Barcelona on February 2007. Presentation of WG4 results and conclusions on the 4 pilot audits, the audit model and the transferability at a European level (please see WG4 Presentations: Annexes D6, D8 and E2).
   - Esteve Trias (TSF)
   - Clara Fernández (TSF)
   - Theo de By (BIS Foundation)


4. Future Activities
a) Dissemination of the Sanco-EQSTB Project, the Guide of Recommendations and the Guide for Auditing Tissue Establishments in diverse local, national and international meetings.

- Dissemination of the Guide for Auditing Tissue Establishments: During the last part of this working period, the Guide for Auditing has been published. 4000 copies have been printed. Some of these have been distributed to all project partners; the rest will be presented and provided to professionals at various international, national and local meetings until the end of the year. The idea is to continue disseminating the Guide until all the copies are distributed. Please see the Project Promoter section of this final report (page 19) for more information on the dissemination of the Guide for Auditing TE.
CONCLUSIONS

The Project Promoter’s role has been crucial regarding the overall management of the project and the small difficulties arisen: need for budget and schedule modifications, assessing of partners, communication with the Commission, etc. The Promoter has made it possible that a good atmosphere and relationship exists among all partners. Throughout the communication platform, partners have been able to communicate with each other and exchange ideas, making them the essential part of the project and participants of the decisions taken.

If we do a balance of what has been achieved during these three years, we see that the objectives set have been fulfilled and very positive results have been obtained. Even some of the tasks set were achieved before the deadlines. The coordinators tasks have been crucial for two main reasons: first, to organize the work in the proper time, and secondly, to obtain consensus among all partners for the different matters arisen. The final meeting that took place in Barcelona on February 2007 allowed explaining face to face the objectives achieved and final conclusions. Likewise, the final activities such as the dissemination of the project outputs and the technical and financial reporting were discussed and planned.

During the life cycle of the project, working group 1 has developed the Guide of Recommendations based on the quality and safety key points of tissue banking, comprising the results from the other working groups. Working Group 2 has produced a prototype of a frozen musculoskeletal tissue registry, proving that it would be possible to exchange tissues among Member States with such a registry. Concerning WG3, a training model for Tissue Bank personnel has been developed, aimed for medical staff and technicians. It includes all the necessary information and skills to guarantee the competence of this staff. As regards to WG4, during this last working period, it has achieved the totality of its work due to the fact that it depended on the results from WGs1-3 and the newly released EU Directive technical annexes. As a result, the Guide for Auditing Tissue Establishments has been developed.
It is essential to maintain the outputs of the project after it finalises. Both the Guide of Recommendations and the Guide for Auditing need a yearly maintenance, to adapt their contents to the new tissue banking concepts and legislations that may emerge. If these guides are not updated and continuously revised, their contents will ‘expire’ shortly. For this reason we recommend that a European body or organisation should be appointed responsible for these tasks. As is detailed in the WGs’ sections, the same issue applies to both the training model and the prototype of frozen musculoskeletal tissue registry.

Detailed below are the conclusions and a set of recommendations that we provide regarding the transferability of the project outputs.

- The Directive Rate of Implementation study should be performed every ‘x’ months so that the EC may see how tissue establishments across Europe are managing the implementation of the European Directives on tissue banking. This issue would be very interesting for the Commission.
- The Guide of Recommendations for Tissue Banking should be continuously updated and its contents further developed, not only as new regulations are created, but also as tissue establishments progress on scientific concepts in the tissue banking field.
- The prototype of frozen musculoskeletal tissue registry that has been developed shows that it would be possible to exchange tissues among European countries with such a registry. Nevertheless, it has been quite challenging to harmonise the variables that are necessary to create a tissue registry and a tissue product list. For this reason, and to be able to exchange tissues throughout member states, it is recommended that a common codification system of tissue products at European level be created.
- The training model, as the Guide of Recommendations, should be updated and its contents extended as new regulations, scientific progress and knowledge on tissue banking issues emerge.
- The Guide for Auditing TE should be maintained and incorporated in a professional audit scheme, which is not currently in existence in Europe. It
needs to have maintenance and a continuous update so that it can be transferred European-wide. It is recommended that for this task, an independent body of auditors be created, a responsibility that could be undertaken by the European Association of Tissue Banks. This organisation could provide this tool to its members, enabling them to organise audits between themselves at their own cost. Perhaps another entity could provide financial support for the performance of TE audits following this Guide in new Member State tissue banks to help them verify compliance with the Directives and to identify priorities for procedural changes.

- For all the outputs detailed above, it is recommended that a body be created responsible for all the tasks mentioned so that these Guides, reports and the training model are of use in the future. These project outputs, unless they are maintained through time, will expire shortly and will not be of much use within a year’s time. Maintenance of these documents and models will be very useful for the EC and for Tissue Establishments, to expand continuously the knowledge and expertise on tissue banking across Europe and to guarantee a high level of quality and safety of tissue banking activities and processes.
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