



Quality of Life and Management of Living Resources

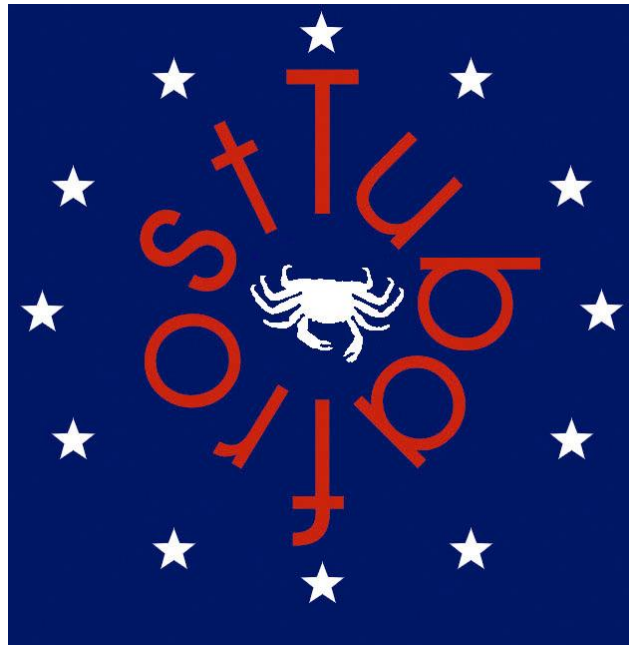
European Human Frozen Tumor Tissue Bank

TUBAFROST

QLRI-CT-2002-01551

Deliverable D 6.3

**Non-profit-making business plan for the European
Human Frozen Tumor Tissue Bank project.**



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Introduction:

The purpose of the present deliverable is to establish what criteria will be necessary for designing a logical, non-profit-making business plan (Task 6.5)¹ for running the TuBaFrost network once the EC support finishes.

In order to carry out this objective a questionnaire was sent to the TuBaFrost consortium in November 2004² (Annex I). The replies were analyzed and discussed in the 5th half-year TuBaFrost meeting in Valencia, 13 and 14th of December 2004 (Annex II).

Analysis and Discussion:

Many possibilities were considered on how to raise starting and running capital for the TuBaFrost network, such as charging a fee for samples, administration costs upon registering requestors, search attempts, requests, and yearly membership, both for requestors and collectors. However, during the business plan discussion it became clear that TuBaFrost needs a period of at least two years to become well known amongst European scientists and collectors. In those two years it is very important that collectors and requestors not be put off by all kinds of financial barriers. Once TuBaFrost is better known after this period by dissemination on the basis of articles and use of scientists throughout over Europe.

The consequence is that in order to survive these two years the consortium needs to find alternative ways of obtaining money for the costs that need to be covered as a bare minimum. The collectors can in that time still collect tissues without any major costs involved, whereas the central database facility needs standard maintenance, assuming the database needs no upgrading or revised versions. In addition, scanning of VM slides takes only a few hours a week while the scanner is doing the actual work. An estimate in the 1st year of € 13,275 and € 13,540 the 2nd year would be the minimum needed.

¹Deliverable D 1.3 & D1.1 Program Handbook & Consortium Agreement

²Minutes of the Tubafrost 5th Half-Year Meeting VALENCIA 13 and 14th of December 2004



On the basis of the sample turnover and number of requests made in these two years a contribution can be based on samples and requests made at the TuBaFrost Central database facility.

In order to establish a price for each requested sample, compensation costs both for collectors and the TuBaFrost network should be considered. In this sense, we defined, what concepts need to be included in the estimation of the direct and indirect costs generated by the processing of stored samples.

These consist of:

Handling of the sample (compensation for collector):

- Sample processing in accordance with to the TuBaFrost Standard Operating Procedures (SOP)^{1, 2}, from when the sample arrives at the department of pathology until it is stored in the tissue repository.
- Maintenance of the sample in the repository.
- Distribution of the tissue to the requestor institutes. It was decided that this concept should not be included in the estimation costs because as was stated by the TuBaFrost consortium: "The collector institutes will be responsible for organizing the sample transportation to the requestor institute. However, the requestor will assume the total costs"^{3, 4}.
- Diagnosis of the sample. It was considered that this would not to be included in the final cost because it is a task that is necessarily done in the context of the clinical management of the patients.

TuBaFrost infrastructure (compensation for TuBaFrost Network):

- Web server maintenance.
- Central office management.
- Virtual tumor bank database.

Hence, taking into account the estimated direct and indirect costs of the collector and the network, as well as the competition in the field⁵, it was

¹TUBAFROST Work Package 3: Protocols and systems for collection and storage of tissue (Deliverable 3.1 June 2003). **Standard Operating Procedure 1:** Protocol for collection of human tumour and corresponding normal tissue.

²TUBAFROST Work Package 3: Protocols and systems for collection and storage of tissue (Deliverable 3.1 June 2003). **Standard Operating Procedure 2:** Protocol for storage of human tumour and corresponding normal tissue

³ Deliverable D 6.2: Policy and rules for monitoring and use of banked tissues in research.

⁴ Milestone D 6.1: Report policy and rules for contribution to and use of banked tumor tissue in research.

⁵Wales Cancer Bank, UK Children's Cancer Study Group



concluded that the estimated price would range from € 70 to € 100 per sample. One question that was raised in this regard was whether all samples should have the same price, given that the final diagnosis of some cases takes much more effort than others. However, it was decided that the price per sample should be about the same, because the efforts involved in making an accurate diagnosis are included in the clinical management of the patient. However, the price of the sample is composed of two parts, the collector's compensation and the TuBaFrost compensation. TuBaFrost provides the opportunity for international collaboration and co-operation. This also carries with it benefits ranging from compensation for the collection, storage and retrieval costs involved, to co-publication, which would depend on negotiations between collector and requestor¹. Adding the TuBaFrost compensation will make up the total price per sample.

It was also considered important to know how many samples would potentially be available each year to the network from each collector institute in order to have an idea of the self-funding capacity of the network. This was not easy to establish, the number of collected samples being between 200 and 1500 samples per year and collector. Considering that not all collected samples would be available for the network, we estimate that the average number of annual available samples from the actual members of TuBaFrost would be at least 3000 samples yearly, but will probably be more. Due to growth we might expect an input of about 10,000 samples a year, with a turnover of 3,000. Asking 20€ per sample for the organisation results in 60,000 €, which already gives TuBaFrost the opportunity to consider employing personnel and updating the website and the database.

In the case that paraffin blocks are requested in addition to frozen material, they must always be returned to the collector, because this material could potentially be required for validation of diagnosis. It is therefore recommended that the blocks can only be shipped temporarily for the production of Tissue Micro

¹ Deliverable D 6.2: Policy and rules for monitoring and use of banked tissues in research.



Arrays. On the other hand, the blocks could be cut at the collector institutes. Extra charges for cutting may range from €7 to €15 per block.

General considerations for the sample price:

It is opportune at this point to remember, as previously stated¹, that samples displayed on the TuBaFrost central database are not 'given away' by the collector to TuBaFrost, but remain in the care of the local collecting centres and of course are available for local use.

Membership contribution:

The objective is for the network to be supported entirely from the income generated by the provision of samples. This means that from the sample price (being the sum of the collector and TuBaFrost compensations), the collector would determine his own compensation separately, depending on the negotiation between the collector and requestor and pay to TuBaFrost their corresponding compensation for the organization of the network. However, this approach is not realistic, at least at the beginning.

It was suggested that collectors could pay an amount to the TuBaFrost organization in advance, as an incentive for collectors to offer good samples to the network, and a yearly membership contribution that could be recovered by income from the samples. However, this was not well received by most of the TuBaFrost collectors, who will be assuming the responsibility for the additional costs once the European Commission support has finished, namely: maintenance of the local tumor bank infrastructure and involved personnel, updating the local and central database, quality controls to ensure the excellence of the stored samples etc. Moreover, this annual contribution was presumed to be high since TuBaFrost is still made up by only a small number of institutions, meaning that the contribution from each TuBaFrost member would be very high.

For this reason, and to prevent deterring potential collectors it was decided that it would be best not to charge a membership fee to collectors, at least during

¹ Milestone D 6.1: Report policy and rules for contribution to and use of banked tumor tissue in research.



the first few years. Finally, it is expected that there will be an increase in sample turnover, as TuBaFrost becomes known in the scientific framework. It was acknowledged that TuBaFrost will only survive such a critical start-up phase through sponsorship. After that period, estimated to be about two years, TuBaFrost will begin charging for their services based upon the tissue turnover and expected maintenance costs. The Organisation of European Cancer Institutes (OECI) and EORTC are seen as potential sponsors, they are being contacted and negotiations are underway.



Annex I: TUBAFROST Questionnaire D6.3

Deliverable 6.3: Not-for-profit business plan for the European Human Frozen Tumor Tissue Bank project (Deadline February 2004).

One task needed to be undertaken to carry out this deliverable:

Task 6.5:

Develop a business plan for running the European Human Frozen Tumor Tissue Bank.

The objective of the present questionnaire is to establish which criteria will be necessary for designing a logical, non-profit and real business plan for the TuBaFrost network. Hence, we would appreciate your answers, as well as all comments that you think could be useful to carry out this task.

- Which concepts would you include in the estimation costs of each sample?
 - Processing: YES/NO
 - Maintenance: YES/NO
 - Distribution of the tissue: YES/NO
 - Web server: YES/NO
 - Diagnosis: YES/NO
 - Central office management: YES/NO
 - Virtual Tumor Bank data base: YES/NO
 - Others (specify):

- Who do you think would have the juridical representation of the TuBaFrost Network in order to be able to emit invoices to the requestor institutes for the requested samples?
 - Each collector
 - Central Office
 - Both

- Who do you think should receive the money for the requested samples?
 - Each collector
 - Central Office
 - Both

- Can you estimate the costs involved in collecting, storing, and retrieving a sample including all steps that must be taken in order to get the right data in the local and the central database? (You have to bear in mind the need for updating the minimum data sheet of every sample). If yes, what is the amount in euros per sample?



- Only for the TuBaFrost Central Office, can you estimate approximately the yearly maintenance costs of the TuBaFrost management?

- Only for the Central Database, can you estimate approximately the yearly maintenance costs of the TuBaFrost central database and web server?

- Should all samples have the same price (thinking that the final diagnosis of some samples has especially taken more efforts than others)? YES/NO.

- Do you think that TuBaFrost members should pay less than non-members per sample? YES/NO. If yes, how much less (in percentage)?

- If paraffin-blocks are requested together with the frozen samples, should they have an additional charge? YES/NO. If yes, how much?

- Do you find it acceptable to pay the TuBaFrost central office a yearly contribution, which could be returned by issuing tissue samples through the TuBaFrost Network? YES/NO.

- If more samples are issued through TuBaFrost and the contribution is earned back, do you think the surplus should go to the TuBaFrost central office to organize the network? YES/NO.

- When do you think that these costs should be paid, after or before the receptor receive the samples?



Annex II: Deliverable 6.3 discussion¹



Work package 6: *Rules for use of stored tissue*

Deliverable 6.3:

Not-for-profit business plan for the European Human Frozen Tumor Tissue Bank project.

Deadline February 2005.

Task 6.5:

Develop a business plan for running the European Human Frozen Tumor Tissue Bank.



Work package 6: *Rules for use of stored tissue*

•Questionnaire D6.3 (November 2004).

•Aim:

- To establish which criteria are necessary for designing a logical, non-profit and real business plan for the TuBaFrost network.

- To cover the basic expenses for the maintenance of the TuBaFrost structure and strategy.



¹ Minutes of the Tubafrost 5th Half-Year Meeting VALENCIA 13 and 14th of December 2004



Work package 6: *Rules for use of stored tissue*

Which concepts would you include in the estimation costs of each sample?

Concepts	EMC	Vienna	Oxford	FIVO
<i>Processing</i>	YES	YES	YES	YES
<i>Maintenance</i>	YES	YES	YES	YES
<i>Distribution of the tissue</i>	YES	YES	YES	YES
<i>Web server</i>	NO	YES	YES	YES
<i>Diagnosis</i>	NO	YES	YES	YES
<i>Central office management</i>	NO	YES	YES	YES
<i>Virtual Tumor Bank data base</i>	NO	YES	YES	YES
<i>Others (specify)</i>	-	-	Quality assurance	-



Work package 6: *Rules for use of stored tissue*

Which concepts would you include in the estimation costs of each sample?

Concepts	EMC	Vienna	Oxford	FIVO
<i>Processing</i>	YES	YES	YES	YES
<i>Maintenance</i>	YES	YES	YES	YES
<i>Distribution of the tissue</i>	YES	YES	YES	YES
<i>Web server</i>	NO	YES	YES	YES
<i>Diagnosis</i>	NO	YES	YES	YES
<i>Central office management</i>	NO	YES	YES	YES
<i>Virtual Tumor Bank data base</i>	NO	YES	YES	YES
<i>Others (specify)</i>	-	-	Quality assurance	-

Requestor
 Prerequisite of the collector





Work package 6: Rules for use of stored tissue

Which concepts would you include in the estimation costs of each sample?

Concepts	EMC	Vienna	Oxford	FIVO
<i>Processing</i>	YES	YES	YES	YES
<i>Maintenance</i>	YES	YES	YES	YES
<i>Distribution of the tissue</i>	YES	YES	YES	YES
<i>Web server</i>	NO	YES	YES	YES
<i>Diagnosis</i>	NO	YES	YES	YES
<i>Central office management</i>	NO	YES	YES	YES
<i>Virtual Tumor Bank data base</i>	NO	YES	YES	YES
<i>Others (specify)</i>	-	-	Quality assurance	-

Intellectual or research benefits



Work package 6: Rules for use of stored tissue

Concepts included in the estimation costs of each sample:

Concepts	EMC	Vienna	Oxford	FIVO
<i>Processing</i>	YES	YES	YES	YES
<i>Maintenance</i>	YES	YES	YES	YES
<i>Web server</i>	NO	YES	YES	YES
<i>Central office management</i>	NO	YES	YES	YES
<i>Virtual Tumor Bank data base</i>	NO	YES	YES	YES





Work package 6: Rules for use of stored tissue

Who would have the juridical representation of the TuBaFrost Network in order to be able to emit invoices to the requestor institutes for the requested samples?

Concepts	EMC	Vienna	Oxford	FIVO
<i>Each collector</i>				
<i>Central office</i>				
<i>Both</i>	X	X	X	X



Work package 6: Rules for use of stored tissue

Who should receive the money for the requested samples?

Concepts	EMC	Vienna	Oxford	FIVO
<i>Each collector</i>	X			X
<i>Central office</i>				
<i>Both</i>		X	X	





Work package 6: Rules for use of stored tissue

Can you estimate the costs involved in collecting, storing, and retrieving a sample including all steps that must be taken in order to get the right data in the local and the central database?

If yes, what is the amount in euros per sample?

Concepts	EMC Vienna	Oxford	FIVO
NO	X	X	
YES			175-250* 15,00 €

*Wales Cancer Bank, UK Children's Cancer Study Group



Work package 6: Rules for use of stored tissue

Only for the TuBaFrost Central Office, can you estimate approximately the yearly maintenance costs of the TuBaFrost management?

Concepts	EMC Vienna	Oxford	FIVO
NO	X	X	X
YES			





Work package 6: Rules for use of stored tissue

Only for the Central Database, can you estimate approximately the yearly maintenance costs of the TuBaFrost central database and web server?

Concepts	EMC	Vienna	Oxford	FIVO
NO	X	X	X	X
YES				



Work package 6: Rules for use of stored tissue

Should all samples have the same price (thinking that the final diagnosis of some samples has especially taken more efforts than others)?

Concepts	EMC	Vienna	Oxford	FIVO
NO			X	X
YES	X	X		X





Work package 6: Rules for use of stored tissue

Do you think that TuBaFrost members should pay less than non-members per sample? YES. If yes, how much less (in percentage)?

Non-members should pay more e.g. 50 % above cost; members at cost.

Principally no, exception: scientific cooperation.



Work package 6: Rules for use of stored tissue

Do you think that TuBaFrost members should pay less than non-members per sample? YES. If yes, how much less (in percentage)?

If TuBaFrost members pay a yearly contribution (tiered system):

- TuBaFrost members (academic/hospital based) could pay 50% less per sample.
- TuBaFrost members (industry/pharmaceutical based) could pay 25% less.
- Academic or hospital-based researchers (non-members) could pay 20% less.
- Industry could pay the whole amount with no reduction.

This would encourage individuals to join TuBaFrost and pay the annual fee.





Work package 6: Rules for use of stored tissue

Do you find it acceptable to pay the TuBaFrost central office a yearly contribution, which could be returned by issuing tissue samples through the TuBaFrost Network?

Concepts	EMC	Vienna	Oxford	FIVO
NO		X		X
YES	X		X	

...but how much?

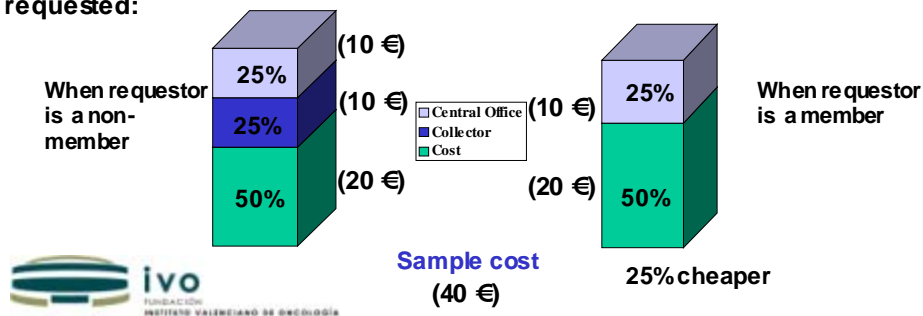


Work package 6: Rules for use of stored tissue

Do you find it acceptable to pay the TuBaFrost central office a yearly contribution, which could be returned by issuing tissue samples through the TuBaFrost Network?

Other possibility:

- Pay to the TuBaFrost Central Office only for the samples that have been requested:





Work package 6: Rules for use of stored tissue

If paraffin-blocks are requested together with the frozen samples, should they have an additional charge?

Concepts	EMC	Vienna	Oxford	FIVO
NO				
YES	10,00 €	?	15-30	X



Work package 6: Rules for use of stored tissue

Are you as a participant willing to pay an amount to the TuBaFrost organization in advance, as an incentive for collectors to offer good samples to the network, which you can earn back or even profit from in the turn over from your samples?

Concepts	EMC	Vienna	Oxford	FIVO
NO		X	X	X
YES	?			





Work package 6: *Rules for use of stored tissue*

How many samples do you hope to offer yearly to the network?

Concepts	EMC	Vienna	Oxford	FIVO
<i>Collected</i>	1000-1500	?	200	400-500
<i>Available</i>	?	?	100	?



Work package 6: *Rules for use of stored tissue*

Additional point to consider:

The cost of the initial Quality Assurance checks on an institute before it can begin collecting within the TuBaFrost network.

As stated in Milestone 6.1 'Participation in the European Human Frozen Tumor Tissue Bank Network will be only possible for those European institutions, which can contribute tissues (collectors). These institutions must, in addition, be able to meet the demands set by the TuBaFrost consortium on minimum standards, protocols and quality control.'





Work package 6: *Rules for use of stored tissue*

Pending points:

- A standard model of invoice
- The yearly maintenance costs of the TuBaFrost Central Office
- The yearly maintenance costs of the TuBaFrost central database and web server
- Establish the yearly contribution to TuBaFrost Central Office
- How can we get funds other than samples?
Advertising industry in the TuBaFrost web page?
Grants?

