Prognostic Test for Breast Cancer Recurrence (PTBCR) Survey Report

for retrieving information on the use of technology in European countries

This document describes the process of retrieving information on the Prognostic Test for Breast Cancer Recurrence technology made via a survey sent to European Countries through EUnetHTA Partner Agencies.

This survey form an integral part of EUnetHTA Joint Action 1- Work Package 4 Core HTA.

Important notice:
This is a FINAL version of the Survey Report. It can be used as reference in the WP4 Core HTA 1 on PTBCR by single domain for integration with the information included in each Domain text.

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Introduction

This report describes the Survey carried out as part of the EUnetHTA Joint Action 1 within Work Package 4 Strand B Core HTA 1 on Prognostic Test for Breast Cancer Recurrence.

The survey was done for getting information on the use of PTCBR in European Countries; the information retrieved was used and integrated by each single Domain in the Core HTA.

Description

During the first phase of the Core HTA project on PTCBR a literature search was made by the researchers working in the 9 domains that compose the Core HTA; following these basic literature review, a need for a further way for gathering information on the technology assessed emerged in different domains.

To complement this low level of data available in the literature, two electronic surveys covering areas in the Organisational Aspects and the Current Use domains of this HTA were developed. One survey was for clinicians and one for lead administrators. Both surveys consisted of mainly multiple choice questions with the option of selecting more than one answer per question. There were 17 questions in the clinician survey and 10 in the administrator survey.

The surveys were developed mainly by NICE, with additional input from members of the two domain teams and Agenas.

A link to the surveys, and a request to identify clinicians and administrators to complete it, was sent by Agenas to the national EUnetHTA agency in all 26 EUnetHTA countries on 14 February 2012. The deadline for completing the surveys was 5 March 2012.
Survey

The following versions are the .doc one of the Survey. The on-line version was set-up with Survey Monkey tool (www.surveymonkey.co); some minor changes in the structure of the survey were made to fit it with restrictions of the web-tool used.

Survey on Prognostic Test for Breast Cancer Recurrence (PTBCR) for CLINICIANS

This questionnaire has been developed for a European collaborative health technology assessment of three genetic tests for breast cancer: uPA/PA1, MammaPrint and Oncotype Dx. The questionnaire only asks about some aspects of the HTA.

This questionnaire is addressed to clinicians who use one of these tests.

1. Which test do you use in your clinic? *This question is required
   - uPA/PA1
   - MammaPrint
   - OncotypeDx

2. Why do you use this test?
   *This question is required
   click on all that apply
   - Patient demand
   - It will be reimbursed
   - It provides additional information to inform clinical decisions
   - It reduces the use of chemotherapy
   - It gives better targeted use of chemotherapy
   - Other (please specify) Please enter an 'other' value for this selection.

3. How do you use the results of this test to inform decisions on the treatment and care of breast cancer patients?
   *This question is required
   click on all that apply
   Always    Often    Sometimes    Rarely    Never
   a. Useful additional information to make chemotherapy treatment decision
   b. Useful additional information to make other types of treatment decision
   c. Determines if patient receives chemotherapy
   d. Determines if patient receives other types of treatment besides chemotherapy
If you use the results of tests to make other types of treatment (row B and D in question 3), please describe the treatment

4. **Who took the decision to introduce the test? *This question is required**
   - Clinician
   - Administrative Staff
   - Other (please describe) Please enter an 'other' value for this selection.

5. **To whom was the decision to introduce the test communicated?**
   *click on all that apply *This question is required
   - Clinicians
   - Administrative Staff
   - Nursing Staff
   - Other (please describe) Please enter an 'other' value for this selection.

6. **Do you feel now that any additional people should have been informed? *This question is required**
   - Yes
   - No (if no, go to question 7)

If YES:
   - Who should have been informed?
   - Why should they have been informed?
   - What should they have been told?

7. **What were the following groups of people told when the test was introduced?**
   - Clinicians
   - Nursing staff
   - Administrative staff

8. **Do you feel now that any of these people should have been given more information?**
   - Yes
   - No (if no, go to question 9)

If yes, what should the following have been told?
   - Clinicians
   - Nursing staff
   - Administrative staff

9. **What kind of unit administers the test in your organisation?**
   - Laboratory
   - Oncological unit
• Other (please describe) Please enter an 'other' value for this selection.

10. What relationship exists between those who prescribe the test and those who administer it?

• Professional advice
• Supply of services
• Part of the same team
• Other (please describe) Please enter an 'other' value for this selection.

11. What relationship exists between those who administer the test and those who interpret the results?

• Professional advice
• Supply of services
• Part of the same team
• Other (please describe) Please enter an 'other' value for this selection.

12. Who decides which tests are made available? *This question is required

• National health care system
• Local health care system
• Insurance company
• Payer
• Clinician
• Other (please describe) Please enter an 'other' value for this selection.

13. Who decides which women are eligible for the test? *This question is required

• National health care system
• Local health care system
• Insurance company
• Payer
• Clinician
• Other (please describe) Please enter an 'other' value for this selection.

14. On what basis is this decision made?

15. How readily was the test adopted by the following groups? *This question is required

   Strong resistance Resistance Acceptance Ready acceptance

   Clinicians
   Nursing staff
   Administrative staff

16. If the test was resisted, what was the nature of the resistance encountered? (Please describe)

17. In your view, what caused the resistance to the use of the test? (Please describe)
Survey on Prognostic Test for Breast Cancer Recurrence (PTBCR) for ADMINISTRATORS

This questionnaire has been developed for a European collaborative health technology assessment of three genetic tests for breast cancer: uPA/PA1, MammaPrint and Oncotype Dx. The questionnaire only asks about some aspects of the HTA.

This questionnaire is addressed to the lead administrator in a clinic where one of these tests is used.

1. Which test do you use in your clinic? *This question is required

   - uPA/PA1
   - MammaPrint
   - OncotypeDx

2. How many tests were carried out in your clinic in the last year? *This question is required
   Number of tests
   from month/year
   to month/year

3. Prior to implementing the test what type of tissue sample were you collecting?

   - Fresh
   - Frozen
   - Formalin Fixed
   - None

4. Was the nature of the sample required (fresh, frozen, formalin fixed) an important part of your decision to adopt the test you did? *This question is required

   - Yes
   - No

5. If you changed methods of sample collection to use this test, what issues and costs did you encounter?

6. In your view, what are the most important management challenge(s) to using this test? Tick all boxes which apply *This question is required

   - Sample collection
   - Sample handling
   - Delay in receiving results
   - Test errors
   - Difficulty in handling reports promptly
   - Persuading practitioners to use the test
   - Improper use of the results
7. How readily was the test adopted by the following groups? *This question is required
   Strong resistanceResistanceAcceptanceReady acceptance
   Clinicians
   Nursing staff
   Administrative staff

8. If the test was resisted, what was the nature of the resistance encountered?

9. In your view, what caused the resistance to the use of the test?

10. What are the most important things to take into consideration for the following groups when planning to introduce the test?
    Clinicians
    Nursing staff
    Administrative staff
Results

The following slides contain the results from responses gathered with the web-tool.

Survey on Prognostic Test for Breast Cancer Recurrence (PTBCR) for CLINICIANS

WP4 Strand B
Genetic Tests for Breast Cancer
Survey for CLINICIANS- Results

AgeNaS

EUnetHTA Joint Action 2010–2012 | www.eunethta.eu

1. Which test do you use in your clinic?

<table>
<thead>
<tr>
<th>Test</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>uPA/PA1</td>
<td>2</td>
<td>25%</td>
</tr>
<tr>
<td>MammaPrint</td>
<td>3</td>
<td>37.5%</td>
</tr>
<tr>
<td>OncotypeDx</td>
<td>6</td>
<td>75%</td>
</tr>
</tbody>
</table>

Total Responses: 7
2. Why do you use this test?

<table>
<thead>
<tr>
<th>Reason</th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>It will be reimbursed</td>
<td>1</td>
<td>12.5%</td>
</tr>
<tr>
<td>It provides additional information to inform clinical decisions</td>
<td>7</td>
<td>87.5%</td>
</tr>
<tr>
<td>It reduces the use of chemotherapy</td>
<td>5</td>
<td>62.5%</td>
</tr>
<tr>
<td>It gives better targeted use of chemotherapy</td>
<td>2</td>
<td>25%</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>2</td>
<td>25%</td>
</tr>
<tr>
<td>Patient demand</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

Total Responses: 8

If you use the results of tests to make other types of treatment - DETAILS:

- The decision is mainly whether to use chemotherapy in addition to endocrine treatment in ER+ women, or endocrine treatment alone (England)
- We used this test only in clinical trial (MINIDACT trial) (Italy - Regione Emilia-Romagna)

3. How do you use the results of this test to inform decisions on the treatment and care of breast cancer patients?

<table>
<thead>
<tr>
<th>Situation</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>Useful additional information to make chemotherapy treatment decision</td>
<td>37.5%</td>
<td>37.5%</td>
<td>25.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Useful additional information to make other types of treatment decision</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>12.5%</td>
<td>87.5%</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Determines if patient receives chemotherapy</td>
<td>25%</td>
<td>25%</td>
<td>37.5%</td>
<td>0.0%</td>
<td>12.5%</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Determines if patient receives other types of treatment besides chemotherapy</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>12.5%</td>
<td>87.5%</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>7</td>
</tr>
</tbody>
</table>

If you use the results of tests to make other types of treatment (row B and D in question 3), please describe the treatment:

- The decision is mainly whether to use chemotherapy in addition to endocrine treatment in ER+ women, or endocrine treatment alone (UK)
4. Who took the decision to introduce the test?

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician</td>
<td>8</td>
<td>100%</td>
</tr>
<tr>
<td>Administrative Staff</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Other (please describe)</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

5. To whom was the decision to introduce the test communicated?

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinicians</td>
<td>6</td>
<td>75%</td>
</tr>
<tr>
<td>Administrative Staff</td>
<td>4</td>
<td>50%</td>
</tr>
<tr>
<td>Nursing Staff</td>
<td>3</td>
<td>37.5%</td>
</tr>
<tr>
<td>Other (please describe)</td>
<td>2</td>
<td>25%</td>
</tr>
</tbody>
</table>

Others:
- Private sector only (UK). Medical Director of the Hospital (Spain, October 12th Hospital of Madrid)
6. Do you feel now that any additional people should have been informed?

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>7</td>
<td>87.5%</td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
<td>12.5%</td>
</tr>
</tbody>
</table>

**YES details:**
- Spain (October 12th Hospital of Madrid)
  - Who should have been informed?: Patient's Associations
  - Why should they have been informed?: To reach equitable access to these tests at different institutions and geographic areas
  - What should they have been told?: Patients should be more informed

7. What were the following groups of people told when the test was introduced?

**Clinicians**
- That the test is available (Slovenia)
- Careful identification of appropriate patients to use the test on and rationale (England)
- That the test would be discussed with relevant patients UK
- The test helps to make therapeutic decisions in some cases (Spain, Hospital General Universitario Gregorio Marañón, Madrid)
- Regional authorities approved Oncotype and MammaPrint availability in selected breast cancer patients. The process has been too long, and clinicians (me in particular at my institution) made a big effort to make them available at each institution. Nevertheless, now there are still too many differences in each hospital in the same area (Madrid, for example) (Spain, October 12th Hospital of Madrid)
- Informed about decision levels, and TAT (Italy – Reg. Veneto)

**Nursing staff**
- Careful identification of appropriate patients to use the test on and rationale (England)
- That the test would be discussed with relevant patients (UK)
- Clinicians have explain the utility of these tests to the nurses (Spain, October 12th Hospital of Madrid)
- Informed about on preanalytical issues (Italy – Reg. Veneto)

**Administrative staff**
- Careful identification of appropriate patients (England)
- Informed about the availability of the test on a study base (free of charge) (Italy – Reg. Veneto)
8. Do you feel now that any of these people should have been given more information?

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>7</td>
<td>100%</td>
</tr>
<tr>
<td>Yes</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

9. What kind of unit administers the test in your organisation?

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory</td>
<td>3</td>
<td>37.5%</td>
</tr>
<tr>
<td>Oncological unit</td>
<td>3</td>
<td>37.5%</td>
</tr>
<tr>
<td>Other (please describe)</td>
<td>3</td>
<td>37.5%</td>
</tr>
</tbody>
</table>

Others:
- Department of pathology (Slovenia)
- Test is sent away to be performed (UK)
- Private sector (UK)
10. What relationship exists between those who prescribe the test and those who administer it?

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply of services</td>
<td>1</td>
<td>12.5%</td>
</tr>
<tr>
<td>Part of the same team</td>
<td>6</td>
<td>75%</td>
</tr>
<tr>
<td>Professional advice</td>
<td>1</td>
<td>12.5%</td>
</tr>
<tr>
<td>Other (please describe)</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

11. What relationship exists between those who administer the test and those who interpret the results?

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional advice</td>
<td>2</td>
<td>25%</td>
</tr>
<tr>
<td>Part of the same team</td>
<td>5</td>
<td>62.5%</td>
</tr>
<tr>
<td>Supply of services</td>
<td>1</td>
<td>12.5%</td>
</tr>
<tr>
<td>Other (please describe)</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
12. *Who decides which tests are made available?*

<table>
<thead>
<tr>
<th>Source</th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>National health care system</td>
<td>2</td>
<td>25%</td>
</tr>
<tr>
<td>Local health care system</td>
<td>3</td>
<td>37.5%</td>
</tr>
<tr>
<td>Insurance company</td>
<td>1</td>
<td>12.5%</td>
</tr>
<tr>
<td>Payer</td>
<td>2</td>
<td>25%</td>
</tr>
<tr>
<td>Clinician</td>
<td>5</td>
<td>62.5%</td>
</tr>
<tr>
<td>Other (please describe)</td>
<td>1</td>
<td>12.5%</td>
</tr>
</tbody>
</table>

*Others:*
* not available on NHS (UK)*

13. *Who decides which women are eligible for the test?*

<table>
<thead>
<tr>
<th>Source</th>
<th>Count</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>National health care system</td>
<td>1</td>
<td>12.5%</td>
</tr>
<tr>
<td>Local health care system</td>
<td>1</td>
<td>12.5%</td>
</tr>
<tr>
<td>Insurance company</td>
<td>1</td>
<td>12.5%</td>
</tr>
<tr>
<td>Payer</td>
<td>1</td>
<td>12.5%</td>
</tr>
<tr>
<td>Clinician</td>
<td>6</td>
<td>75%</td>
</tr>
<tr>
<td>Other (please describe)</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
14. On what basis is this decision made?

- Availability, funding and potential clinical benefit (England)
- Offered on a case by case basis to women at intermediate risk of breast cancer who are struggling to make a decision around adjuvant chemotherapy (UK)
- Medical literature (Spain, Hospital General Universitario Gregorio Marañón, Madrid)
- The local health care system decides which patients will not have to pay for the tests, if they meet the inclusion clinical criteria defined by the local authorities (Consejería de Sanidad de la Comunidad de Madrid-Regional Health Care Administration of Madrid Region) (Spain, October 12th Hospital of Madrid)
- Evidence based Cost analysis based Resources allotment prioritization based (Italy – Reg. Veneto)
- Patients with characteristics to be enrolled in MINDACT trial (Reg. Emilia Romagna)
15. How readily was the test adopted by the following groups?

<table>
<thead>
<tr>
<th></th>
<th>Strong resistance</th>
<th>Resistance</th>
<th>Acceptance</th>
<th>Ready acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinicians</td>
<td>0.0%</td>
<td>12.5%</td>
<td>37.5%</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Nursing staff</td>
<td>0.0%</td>
<td>12.5%</td>
<td>25%</td>
<td>62.5%</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Administrative staff</td>
<td>0.0%</td>
<td>25%</td>
<td>50%</td>
<td>25%</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

16. If the test was resisted, what was the nature of the resistance encountered?

- Anxiety about offering a test to the patient that they would need to pay for (UK)
- Fear of immediate cost increase (Spain)
- not available NHS (UK)
- low perception of clinical usefulness (Italy – Reg. Veneto)
- Problems for transport and preservation of samples. Costs (Reg. Emilia-Romagna)
17. In your view, what caused the resistance to the use of the test?

- Patient has to pay a large amount of their own money (UK)
- Lack of confidence in cost/effectiveness (Spain)
- Not advocated strongly by clinicians as use limited and expensive (UK)
- No requirement of the target test in clinical trials on adjuvant therapy in which the majority of are actually enrolled (Italy – Reg. Veneto)
- need to wait for the data of clinical trials (TailoRX, MINDACT) to define the role and necessity of these tests in therapeutic decision (Reg. Emilia-Romagna)
1. Which test do you use in your clinic?

<table>
<thead>
<tr>
<th>Test</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>uPA/PA1</td>
<td>1</td>
<td>33%</td>
</tr>
<tr>
<td>MammaPrint</td>
<td>1</td>
<td>33%</td>
</tr>
<tr>
<td>OncotypeDx</td>
<td>1</td>
<td>33%</td>
</tr>
</tbody>
</table>

2. How many tests were carried out in your clinic in the last year?

<table>
<thead>
<tr>
<th>Location</th>
<th>Activity Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain</td>
<td>5-6 per month in the last 6 months</td>
</tr>
<tr>
<td>Italy (Reg. Veneto)</td>
<td>Number of tests: 914 from month/year: Feb/2004 to month/year: April/2009</td>
</tr>
</tbody>
</table>

Total Responses: 2 (Italy, Spain)

3. Prior to implementing the test what type of tissue sample were you collecting?

- Formalin Fixed (Spain)
- Frozen (Italy)

4. Was the nature of the sample required (fresh, frozen, formalin fixed) an important part of your decision to adopt the test you did?

Spain: No
Italy: Yes

Total Responses: 2 (Italy, Spain)
5. *If you changed methods of sample collection to use this test, what issues and costs did you encounter?*

Spain: We have had previous experiences with frozen tissue for MammaPrint into MiNDACT trial, so this was already implemented. Nowadays, MammaPrint can be done in formalin fixed tissue, so the technical issues are equal as for Oncotype.

6. *In your view, what are the most important management challenge(s) to using this test?*

Sample collection (Italy)
Sample handling (Italy, Spain)
Delay in receiving results (Italy, Spain)
Persuading practitioners to use the test (Italy, Spain)

7. *How readily was the test adopted by the following groups?*

<table>
<thead>
<tr>
<th></th>
<th>Strong resistance</th>
<th>Resistance</th>
<th>Acceptance</th>
<th>Ready acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinicians</td>
<td></td>
<td>✓ (Italy)</td>
<td></td>
<td>✓ (Spain)</td>
</tr>
<tr>
<td>Nursing staff</td>
<td></td>
<td></td>
<td></td>
<td>✓ (Italy, Spain)</td>
</tr>
<tr>
<td>Administrative staff</td>
<td></td>
<td></td>
<td>✓ (Italy, Spain)</td>
<td></td>
</tr>
</tbody>
</table>
8. If the test was resisted, what was the nature of the resistance encountered?

Italy: low perception of clinical usefulness

9. In your view, what caused the resistance to the use of the test?

Italy: No requirement of the target test in clinical trials on adjuvant therapy in which the majority of are actually enrolled

10. What are the most important things to take into consideration for the following groups when planning to introduce the test?

**Clinicians:**
- Italy: clinical usefulness
- Spain: Information about clinical trials and validations. Information on patient heterogeneity and long-term costs and toxicities derived from chemotherapy.

**Nursing staff:**
- Spain: How to handle samples and send them to reference laboratories.

**Administrative staff:**
- Italy: cost saving IF used to reduce unnecessary chemotherapy
- Spain: Basic information
Background of the project

In 2005 the first project of establishing a sustainable European Network on Health Technology Assessment (HTA) was set up with funds from the European Commission and the Council of Ministers; the first project included a group of 35 organizations in 27 European countries with the coordination of the Danish Centre for Evaluation and HTA.

The main strategic objective of the network was to actively connect different HTA agencies and institutions, at national and/or regional level, in order to enable an effective exchange of information and to support policy makers decisions. The first step was to set-up an organizational framework for a European Network on HTA and the development of practical tools and services.

After the successful completion of the EunetHTA Project (2006-2008) the EUnetHTA Collaboration further developed the pillars for a sustainable and permanent collaboration for HTA in Europe. In 2009 25 Founding Partners of EUnetHTA Collaboration joined forces with other partners and the European Commission to implement results of the previous projects through a Joint Action on HTA 2010-2012: a total of 55 organisation committed their resources to participate in the planned activities within the framework of the EunetHTA Joint Action.

The overarching objective of the EUnetHTA Joint Action 2010-2012 (JA) is to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level.

In October 2012 a second Joint Action will start and it will led to the creation of a permanent and sustainable European Network for HTA through the development of a general strategy, principals and an implementation proposal, according to the requirements of Article 15 of the Directive for cross-border healthcare.