# *Balloon Eustachian tuboplasty for the treatment of Eustachian tube dysfunction*

## *Project ID: WP5-SB-13*

## Project description and planning

May 16th, 2014

**Authors: THL, Co-authors: HIQA**

# Contents:

# A. VERSION LOG

| Version number | Date | Name (Initials) | Modification | Reason for the modification |
|---|---|---|---|---|
| V1 | 08/04/14 | SS/TK | First version of the project plan. | Sent to co-authors, deadline 15/04/14 |
| V2 | 17/04/14 | SS/TK | Second version of the project plan. | Comments of co-authors have been incorporated. Sent to dedicated reviewers and external reviewers deadline 05/05/14 |
| V3 | 06/05/14 | | Third version of the project plan | E-meeting |
| V4 | 16/05/14 | SS/TK | Fourth version of the project plan for public consultation. | Comments from dedicated reviewers and the e-meeting have been incorporated. Sent for public consultation on 19/05/2014. |
| V5 | 19/06/14 | SS/TK | Fifth version of the project plan. | Comments from the public consultation have been incorporated. |

# B. PROJECT PLAN

## 1.0 PARTICIPANTS

Table 1. Project participants

| # | Agency | Role in the project | Individual's expertise | Country |
|---|---|---|---|---|
| 1. | THL, National Institute for Health and Welfare, Finohta | Author(s) | public health, pharmacy, health services research<br>medicine, pharmacology, neurology | Finland |
| 2. | HIQA, Health Information and Quality Authority | Co-Author(s) | health economics<br>health service research, pharmacy<br>Surgery, medicine, ENT | Ireland |
| 3. | HVB, Association of Austrian Social Insurance Institutions | Reviewer | medicine, public health, nutrition/dietetics | Austria |
| 4. | GYEMSZI, National Institute for Quality- and Organizational Development in Healthcare and Medicines | Reviewer | medicine, health economics, medical device | Hungary |
| 5. | AHTAPol, Agency for Health Technology Assessment in Poland | Reviewer | pharmacy, health economics, systematic reviews | Poland |
| 6. | HUS - The Hospital District of Helsinki and Uusimaa<br>OUH - Oslo University Hospital | External Reviewer 1<br><br>External Reviewer 2 | medicine, ENT<br><br>medicine, ENT | Finland<br><br>Norway |
| 7. | TBD | Medical Editor | | |
| 8. | LBI-HTA - Ludwig Boltzmann Institute for HTA | Project Coordinator | Project management | Austria |

## 1.1 PROJECT STAKEHOLDERS

Table 2. Project stakeholders

| Organisation | Contact (name, e-mail, tel) | Comments |
|---|---|---|
| Spiggle & Theis Medizintechnik GmbH | Susanne Ferfers<br>telephone: +49 (0) 2206 / 9081 - 53<br>e-mail: s.ferfers@spiggle-theis.de | Spiggle&Theis has the first CE-marked balloon catheter for BET on the market, the 'Bielefelder Ballonkatheter' |
| Acclarent Inc. | Michael Mc Cormack<br>telephone: 901 341 3841<br>e-mail: mmccor@its.jnj.com | Acclarent Inc. has obtained CE mark for their Eustachian tube dilation technology on May 8th, 2014. |

## 2.0 PROJECT INTRODUCTION/ RATIONALE

| Project introduction/ rationale |
|---|
| The rationale for this pilot assessment report is to test the capacity of national HTA bodies to collaboratively produce structured rapid core HTA information on pharmaceuticals (strand A) and other medical technologies, such as medical devices, surgical interventions or diagnostics (strand B). In addition, the application (translation) of those collaboratively produced HTAs in the national contexts will be tested**.** |

## 3.0 PROJECT SCOPE AND OBJECTIVES

| | **List of project objectives** | **Indicator (and target)** |
|---|---|---|
| 1. | To test the capacity of national HTA bodies to collaboratively produce structured rapid core HTA | Production of 1 pilot rapid assessment according to the research question (see Table 3) |
| 2. | To test the application of these collaboratively produced rapid assessments into a national/local context | Production of ≥1 national/local report per pilot rapid assessment |
| 3. | To test on-line tool for rapid assessment | Gain experience of the on-line tool and identify possible areas for improvement |
| 4. | To compile a pilot rapid assessment on balloon Eustachian tuboplasty (BET) for the treatment of Eustachian tube dysfunction. | Production of an assessment on balloon Eustachian tuboplasty for the treatment of Eustachian tube dysfunction. The treatment is increasingly being promoted and the potential patient group is large. The procedure is invasive and needs general anesthesia. There is a potential risk of life-threatening complications due to puncture of the carotid artery. |

This pilot rapid assessment addresses the research question whether balloon Eustachian tuboplasty (BET) in adolescents and adults having Eustachian tube dysfunction is more effective and/or safer than standard care including tympanostomy or medication.

Table 3. Project Scope: PICO

| **Description** | **Project scope** |
|---|---|
| **Population** | ICD-10 codes: H65.3 Chronic mucoid otitis media, H65.2 Chronic serous otitis media/ otitis media with effusion (OME), H68.1 Obstruction of Eustachian tube,H65.4 Other chronic nonsuppurative otitis media, H65.9 Nonsuppurative otitis media, unspecified, H69.9 Eustachian tube disorder, unspecified.<br>• MeSH terms: Ear Diseases, Eustachian Tube<br>• Target population: Adolescents over 12 years and adults with otitis media with effusion (OME), middle ear |

| | |
|---|---|
| | atelectasis or chronic Eustachian tube dysfunction (ETD) (muffled hearing, pain, feeling of fullness in the ear, tinnitus and dizziness) and other indications mentioned above. The target population covers obstructive (non-patulous) or dilatory dysfunction of the Eustachian tube. ETD needs to be confirmed by objective measure (nasal endoscopy, audiology examinations or radiographic imaging).<br><br>• Mesh-terms: Humans, Adult, Adolescent, Ear, Middle Ear, Ear diseases<br>• Intended use of the technology: Treatment |
| **Intervention** | In Balloon Eustachian Tuboplasty (BET), a balloon catheter is introduced in to the Eustachian tube via the nose under general anesthesia. Once the balloon is correctly positioned in the cartilaginous part of the Eustachian tube, it is filled with saline up to a pressure of 10 bars. Pressure is maintained for approximately 2 minutes and then the liquid is aspirated and the catheter removed (Spiggle & Theis). For the catheter produced by Acclarent Inc., the cartilaginous position of the Eustachian tube is dilated with a balled catheter where endoscopic markers are placed among the subject device to aid in positioning under direct endoscopic visualization (Acclarent Inc.).<br><br>MeSH term*:* Eustachian tuboplasty, Dilatation, Balloon dilatation, Ventilation |
| **Comparison** | • Tympanostomy (ventilation tube, grommet)<br>• Medication (to decrease oedema of the nasopharynx; nasal decongestants, antihistamines, leukotriene receptor antagonists, simethicone, oral or nasal corticosteroids, antibiotics, nasal douching, transtubal fluids)<br><br>MeSH-terms: Middle Ear Ventilation |
| **Outcomes** | Primary:<br>Normalization of tympanometry measures<br><br>Secondary:<br>Middle ear function, measured by Valsalva manoeuvre, or other tests like Toynbee test and tubomanometry (TMM).<br>Audiometric evaluation of hearing function,<br>Pressure swallow test<br>Tube score,<br>Clearance of middle ear effusion,<br>Need for additional treatment<br>Quality of life<br><br>For long term efficacy: frequency of hearing loss, otitis media, tympanic membrane perforations, cholesteatomas and complications of otitis media (eg. meningitis)<br><br>Adverse effects (early complications, late adverse effects, treatment related adverse effects, serious adverse events)<br><br>The outcomes were selected according to the earlier literature on the topic (1-9). |

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|---|---|
| **Study design** | RCTs, non-randomised trials, prospective trials, controlled observational studies, case series with ≥ 10 patients |

## 4.0 PROJECT APPROACH AND METHOD

Table 4a. Project approach and method

| **Project approach and method** |
|---|
| This rapid assessment is based on the assessment elements from the HTA Core Model for rapid REA of pharmaceuticals and on a systematic literature review from the following sources:<br>- Medline via OVID, EMBASE<br>- Cochrane database, DARE and HTA databases via the Cochrane Library and CDR<br>- WHO International Clinical trials Registry Platform (ICTRP) and ClinicalTrials.gov for the identification of registered clinical trials.<br>- Information from the manufacturers.<br><br>Studies and other relevant data sources will be selected by the researchers at the agency who will answer research questions of the domain they are primarily responsible for. Inclusion and exclusion of the studies is based on PICO. Accepted study design for “Clinical effectiveness” include: randomised controlled trials, non-randomised trials, controlled observational studies, case series with ≥ 10 patients.<br><br>Inclusion by patient population: Studies including adults and/or adolescents over 12 years are included. Symptomatic patients with Eustachian tube dysfunction need to be confirmed by objective measure (nasal endoscopy, audiology examination, or radiographic imaging).<br><br>Exclusion by indication/population: children < 12 years, patients with patulous dysfunction of the Eustachian tube.<br><br>Exclusion by intervention: laser Eustachian tuboplasty, combined interventions.<br><br>For the “Safety” domain, also case studies and cadaver studies are accepted.<br>For the “Health problem and current use of the technology” and “Description and technical characteristics” domains, no restrictions in terms of study design are applied. Additional searches and database information, such as databases for clinical guidelines, register data can be used on the “Health problem and current use of the technology” and “Description and technical characteristics” domains.<br><br>Quality assessment for systematic reviews is based on: PRISMA (10). For the randomised controlled trials and non-randomised studies the EPOC risk of bias checklist (11) is used: For the case series appraisal a 18-criteria checklist by IHE is used (12).<br><br>Distribution of work between author (THL) and co-author (HIQA): |

THL tasks are:

- responsibility for the coordination of the work
- to develop the first draft of the project plan
- to develop the scientific process plan with specific tasks to be carried out, time frames and deadlines of milestones and deliverables
- perform the basic literature search
- involve clinical expert(s)
- carry out the assessment on the domains: " Clinical effectiveness" and "Safety"
- perform assessment of ethical and organizational aspects if needed
- review assessments of the co-author
- send the 2nd draft version to reviewers,
- compile feedback from reviewers and stakeholders and make changes according to reviewers' and stakeholders' comments
- compile all domains in to a final report and write the final summary of the assessment.

HIQA tasks are:

- review the draft project plan
- carry out assessment on the domains: "Health problem and Current use of the technology" and "Description and technical characteristics of technology"
- carry out a search from EMBASE based on a given literature search protocol by Finohta
- review other domain assessments made by THL
- review final version of the assessment/review

Table 4b. Preliminary Evidence

| **Preliminary evidence table** |
|---|
| Author, year, reference, country |
| Sponsor |
| Intervention |
| Comparator |
| Study design |
| Number of patients/ears |
| Patient characteristics: age, diagnosis |
| Diagnostic methods used |
| Previous treatments |
| Follow up (mean+SD, weeks, months) |
| Author disclosure (conflict- of –interest) |

**Efficacy outcomes**
Change in severity and or frequency of symptoms (symptoms scores, resolution of symptoms %)
Hearing improvement (air-bone gap, measurement of hearing dB)
Middle ear functioning (tympanometry, Valsalva manoeuvre, pressure swallow test)
Need for additional treatment (medication, grommets, repeated dilatation, other procedures)
Quality of life

**Safety**
Any complication/adverse event, n, %
Serious adverse events, n, %
Description of adverse events

## Selected assessment elements

Table 5. Assessment elements and translating research questions

| ID | Domain | Topic | Issue | Relevance in this assessment Yes/No | Reason for non-relevance/ Preliminary research question(s) | Source of assessment element |
|---|---|---|---|---|---|---|
| **Health problem and current use of technology** | | | | | | |
| A0002 | Health Problem and Current Use of the Technology | Target Condition | What is the disease or health condition in the scope of this assessment? | Yes | What is the definition of Eustachian tube dysfunction (ETD), glue ear according to ICD-10? | REA Model in all |
| A0003 | Health Problem and Current Use of the Technology | Target Condition | What are the known risk factors for the condition? | Yes | What factors causes Eustachian tube dysfunction or glue ear? | |
| A0004 | Health Problem and Current Use of the Technology | Target Condition | What is the natural course of the condition? | Yes | What is the natural course of Eustachian tube dysfunction and glue ear? | |
| A0005 | Health Problem and | Target Condition | What is the burden of disease for the patient? | Yes | What is burden of Eustachian tube dysfunction and glue ear for the patient? | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Current Use of the Technology | | | | How does Eustachian tube dysfunction, glue ear affect the daily life of the patient? | |
| A0006 | Health Problem and Current Use of the Technology | Target Condition | What is the burden of the disease for society? | Yes | Not a serious condition which causes early retirement etc. | |
| A0007 | Health Problem and Current Use of the Technology | Target Population | What is the target population in this assessment? | Yes | What is the target population in this assessment? | |
| A0023 | Health Problem and Current Use of the Technology | Target Population | How many people belong to the target population? | Yes | What is the prevalence of the condition? | |
| A0001 | Health Problem and Current Use of the Technology | Utilisation | For which health conditions and populations, and for what purposes is the technology used? | Yes | For which indications or symptoms is balloon Eustachian tuboplasty used and in which patient groups? | |
| A0011 | Health Problem and Current Use of the Technology | Utilisation | How much are the technologies utilised? | Yes | How widely is balloon Eustachian tuboplasty being used in Europe? | |
| A0024 | Health Problem and Current Use of the Technology | Current Management of the Condition | How is the health condition currently diagnosed according to published guidelines and in practice? | Yes | How are Eustachian tube dysfunction and glue ear diagnosed according to clinical practice guidelines and in practice? | |
| A0025 | Health Problem and Current Use of the Technology | Current Management of the Condition | How is the health condition currently managed according to published guidelines and in practice? | Yes | How are Eustachian tube dysfunction and glue ear managed according to clinical practice guidelines and in practice? | |
| A0020 | Health Problem and Current Use of the Technology | Regulatory Status | What is the marketing authorisation status of the technology? | Yes | What is the marketing authorisation status of balloon Eustachian tuboplasty catheters in Europe? | |
| A0021 | Health Problem and | Regulatory Status | What is the reimbursement status of the technology? | Yes | What is the reimbursement status of balloon Eustachian tuboplasty catheters in Europe? | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Description and technical characteristics of technology** | | | | | | |
| B0001 | Description and technical characteristics of technology | Features of the technology | What is the technology and the comparator(s)? | Yes | What is balloon Eustachian tuboplasty (BET) and what are the treatment alternatives? | |
| B0002 | Description and technical characteristics of technology | Features of the technology | What is the approved indication and claimed benefit of the technology and the comparator(s)? | Yes | What are the approved indications and claimed benefits of BET and the treatment alternatives? | |
| B0003 | Description and technical characteristics of technology | Features of the technology | What is the phase of development and implementation of the technology and the comparator(s)? | Yes | What is the phase of development and implementation of BET and the treatment alternatives)? | |
| B0004 | Description and technical characteristics of technology | Features of the technology | Who performs or administers the technology and the comparator(s)? | Yes | Who performs or administers BET and the treatment alternatives? | |
| B0005 | Description and technical characteristics of technology | Features of the technology | In what context and level of care are the technology and the comparator used? | Yes | In what context and level of care are BET and the treatment alternatives used? | |
| B0008 | Description and technical characteristics of technology | Investments and tools required to use the technology | What kind of special premises are needed to use the technology and the comparator(s)? | Yes | What kind of special premises are needed to use BET and the treatment alternatives? | |
| B0009 | Description and technical characteristics of technology | Investments and tools required to use the technology | What supplies are needed to use the technology and the comparator? | Yes | What supplies are needed to use BET and the alternative treatments? | |
| B0010 | Description and technical characteristics of technology | Investments and tools required to use the technology | What kind of data and records are needed to monitor the use of the technology and the comparator? | Yes | What kind of data and records are needed to monitor the use of BET and the other treatment alternatives? | |
| B0011 | Description and technical characteristics of technology | Investments and tools required to use the technology | What kind of registry is needed to monitor the use of the technology and comparator? | Yes | What kind of registry is needed to monitor the use of BET and treatment alternatives? | |
| **Safety** | | | | | | |
| C0001 | Safety | Patient safety | What kind of harms can use of the technology cause to the patient? | Yes | What kind of harms can use of balloon Eustachian tuboplasty cause to the patient? | |
| C0002 | Safety | Patient safety | What is the dose | No | No dose-relationship here. (including | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | relationship of the harms? | | intensity or length or treatment) | |
| C0004 | Safety | Patient safety | How does the frequency or severity of harms change over time or in different settings? | Yes | Are there differences in the frequency and severity of adverse events (harms) over time or according to treatment setting? | |
| C0005 | Safety | Patient safety | What are the susceptible patient groups that are more likely to be harmed? | Yes | Are there any patient sub-groups that are more likely to be harmed? | |
| C0007 | Safety | Patient safety | What are the user-dependent harms? | Yes | Are there user-dependent harms caused by providers (surgeons) | |
| C0008 | Safety | Patient safety | How safe is the technology in relation to the comparator? | Yes | What is the safety of the balloon Eustachian tuboplasty compared to standard of care (tympanostomy or medication)? | |
| C0040 | Safety | Environmental safety | What kind of harms are there for public and environment? | No | None | |
| **Clinical effectiveness** | | | | | | |
| D0001 | Clinical effectiveness | Mortality | What is the expected beneficial effect of the intervention on overall mortality? | No | Balloon Eustachian tuboplasty does not have beneficial effect on mortality | |
| D0002 | Clinical effectiveness | Mortality | What is the expected beneficial effect on the disease-specific mortality? | No | Balloon Eustachian tuboplasty does not have beneficial effect on mortality | |
| D0005 | Clinical effectiveness | Morbidity | How does the technology affect symptoms and findings? | Yes | How does balloon Eustachian tuboplasty affect symptoms and findings? | |
| D0006 | Clinical effectiveness | Morbidity | How does the technology affect progression of disease? | Yes | How does BET affect progression of Eustachian tube dysfunction?( more questions of yes/no symptoms, not progression?) | |
| D0011 | Clinical effectiveness | Function | What is the effect of the technology on patients' body functions? | Yes | What is the effect of BET on patients' body functions (e.g. hearing) | |
| D0016 | Clinical effectiveness | Function | How does the use of technology affect activities of daily living? | Yes | How does the use of BET affect activities of daily living? | |
| D0012 | Clinical effectiveness | Health-related quality of life | What is the effect of the technology on generic health-related quality of life? | Yes | What is the effect of BET on generic health-related quality of life? | |
| D0013 | Clinical effectiveness | Health-related quality of life | What is the effect of the technology on disease- | Yes | What is the effect of BET on disease-specific quality of life? | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | specific quality of life? | | | |
| D0017 | Clinical effectiveness | Patient satisfaction | Was the use of the technology worthwhile? | Yes | Were patients satisfied with the BET outcomes? | |
| D0023 | Clinical effectiveness | Change in management | How does the technology modify the need for other technologies and use of resources? | Yes | How does balloon Eustachian tuboplasty modify need for other technologies and use of resources? | HTA Core Model for Diagnostic Technologies |

## Checklist for potential ethical, organisational, social and legal aspects

Table 6. Checklist for potential ethical, organisational, social and legal aspects.

| | |
|---|---|
| **1. Ethical** | |
| 1.1. Does the introduction of the new technology and its potential use/nonuse instead of the defined, existing comparator(s) give rise to any new ethical issues? | No |
| 1.2. Does comparing the new technology to the defined, existing comparators point to any differences which may be ethically relevant? | No |
| | |
| **2. Organisational** | |
| 2.1. Does the introduction of the new technology and its potential use/nonuse instead of the defined, existing comparators require organisational changes? | No |
| 2.2. Does comparing the new technology to the defined, existing comparators point to any differences which may be organisationally relevant? | No |
| | |
| 3. **Social**: | |
| 3.1. Does the introduction of the new technology and its potential use/nonuse instead of the defined, existing comparator(s) give rise to any new social issues? | No |
| 3.2. Does comparing the new technology to the defined, existing comparators point to any differences which may be | No |

| | |
|---|---|
| socially relevant? | |
| | |
| 4. **Legal**: | |
| 4.1. Does the introduction of the new technology and its potential use/nonuse instead of the defined, existing comparator(s) give rise to any legal issues? | No |
| 4.2. Does comparing the new technology to the defined, existing comparators point to any differences which may be legally relevant? | No |
| | |

## 5.0 ORGANISATION OF THE WORK

## 5.1 MILESTONES AND DELIVERABLE(S)

Table 7. Milestones and Deliverables

| **Milestones/Deliverables** | **Start date** | **End date** |
|---|---|---|
| **Project duration** | **01/04//2014** | **12/12/2014** |
| Pilot's team building | 07/02/2014 | 28/02/2014 |
| **Scoping phase** | **01/04/2014** | **19/06/2014** |
| Consultation of draft project plan with co-authors | 10/04/2014 | 18/04/2014 |
| Consultation of draft project plan with dedicated reviewers | 28/04/2014 | 14/05/2014 |
| Consultation of draft Project Plan (public consultation including WP5 SAG, SF and manufacturer(s)) | 19/05/2014 | 06/06/2014 |
| Final Project Plan | 06/06/2014 | 19/06/2014 |
| **Assessment phase** | **19/06/2014** | **12/12/2014** |
| First draft available | 19/06/2014 | 25/08/2014 |
| Review by dedicated reviewers | 25/08/2014 | 08/09/2014 |
| Second draft available | 08/09/2014 | 29/09/2014 |
| Review by ≥ 1 external clinical expert, manufacturer(s), by Strand B members and other potential stakeholders | 29/09/2014 | 20/10/2014 |
| Third draft available | 20/10/2014 | 11/11/2014 |
| Medical Editing | 17/11/2014 | 28/11/2014 |
| Fourth draft available | 01/12/2014 | 05/12/2014 |

| | | |
|---|---|---|
| Formatting | 08/12/2014 | 12/12/2014 |
| **Final pilot assessment** | | **week from 15/12/2014** |
| **Local Reports (if applicable)** | | |
| Local (national or regional) REA N°1 [THL, Finland] | | |
| Local (national or regional) REA N°2 [HBV, Austria] | | |
| Local (national or regional) REA N°2 [GYEMSZI, Hungary] | | |

## 5.2 MEETINGS

Besides face-to-face meetings mentioned in the Work Plan of WP5, no further face-to-face meetings are planned for this specific project.
Up to 4 e-meetings may be scheduled for this pilot rapid assessment (see section 6.0), if considered necessary.

## 6.0 COMMUNICATION

Table 8. Communication

| Communication Type | Description | Date | Format | Participants/ Distribution |
|---|---|---|---|---|
| **Draft Project Plan with timelines** | Review of methods and assessment elements chosen, discussion of time-lines | [06/05/2014] | E-mail | Author(s), Co-author(s), dedicated reviewers, Coordinating Team |
| **Final Project Plan** | Review of methods and assessment elements chosen, discussion of time-lines considering comments from Stakeholder Advisory Group, public, manufacturer | [13/06/2014] | E-mail | Author(s), Co-author(s), dedicated reviewers, Coordinating Team |
| **First draft of the pilot assessment** | To be reviewed by dedicated reviewers | [25/08/2014] | E-mail (e-meetings to be planned here -optional) | Dedicated reviewers |
| | To discuss comments of dedicated reviewers (optional) | [ 10/09/2014YY] | E-Mail (e-meetings to be planned here -optional) | Author(s), co-author(s), dedicated reviewers |
| **Second draft of the pilot assessment** | To be consulted with ≥1 clinical expert, WP5 members, manufacturer(s), other potential stakeholders | [29/092014] | E-mail | ≥1 clinical expert, WP5 members, manufacturer, other potential stakeholders |

| | | | | |
|---|---|---|---|---|
| **Final pilot rapid assessment** | Medical editing by external editor | [17/11/2014] | E-Mail | Medical Editor |

## 6.1 DISSEMINATION PLAN

The final pilot rapid assessment will be distributed as laid-out in the Work Plan of WP5.

## 7.0 COLLABORATION WITH STAKEHOLDERS

A public consultation of the draft Project Plan will be conducted. The draft Project Plan will be made publicly available on the EUnetHTA website for a period of 15 days. The WP5 SAG, the Stakeholder Forum as well as the manufacturer(s) will be invited to comment on the draft Project Plan for this pilot rapid assessment.
In addition, the manufacturer will be asked for further information (e.g. C/E mark, on-going studies, available evidence, reimbursement status).

## 8.0 COLLABORATION WITH EUnetHTA WPs

For the individual pilot rapid assessment, no collaboration with other WPs is planned.

## 9.0 RESOURCE PLANNING

## 9.1 HUMAN RESOURCES

Table 9. Human resources

| **Role** | **Total number of person days** | **Source** | |
|---|---|---|---|
| | | **Staff of participating organisations** | **Subcontracting** |
| **Author** | 60 person days | 60 person days | - |
| **Co-Author** | 30 person days | 30 person days | - |
| **Reviewer** | 3 person days each | 3 person days each | - |
| **External reviewer** | 8 person days | - | 8 person days |
| **Medical Editor** | 5 person days | - | 5 person days |
| **Layout** | 4 person days | - | 4 person days |

## 10.0 CONFLICT OF INTEREST MANAGEMENT

Conflicts of interest will be handled according to EUnetHTA JA2 Conflict of Interest Policy. As conflict of interest may be topic dependent, conflict of interest declarations will be collected from authors and reviewers involved in a specific pilot assessments. Authors and reviewers who declare a conflict of interest will be excluded from parts of, or the whole work under this specific topic. However, they may still be included in other pilots.
If external experts are involved in WP5 a conflict of interest declarations will be collected from them regarding the topic. External experts who declare a conflict of interest will be excluded from parts of, or the whole work under this specific topic. However, they may still be included in other pilots.

## 11.0 EXPECTED OUTCOME(S)

| **Project outcome(s)** |
|---|
| The capacity of national HTA bodies to collaboratively produce structured rapid core HTA.<br>Translation into local reports immediately and later. Redundancies is reduced and efficiency gains achieved.<br>Applicability of the HTA Core Model for rapid REAs to other technologies is elicited and the Model accordingly adapted.<br>On-line tool will be tested in the rapid assessment for the first time. |

# C. REFERENCES


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