RENAL DENERVATION SYSTEMS FOR TREATMENT-RESISTANT HYPERTENSION

PROJECT PLAN

Project description and planning

Pilot ID: WP5-SB-12

Authors: NOKC
Co-Authors: Avalia-t, CR.DK

CONTENT

VERSION LOG

Version number	Date	Name (Initials)	Drafts and modifications	Comments and reason(s) for modifications if relevant
V1	10/05/13	KBF /TR	First version of project plan	Sent to co-authors for comments with deadline 15/05/2013.
V2	16/05/13	KBF/ TR	Second version of project plan (minor modifications)	Sent to reviewers for comments with deadline 23/05/2013.
V3	28/05/13	KBF/ TR	Third version of project plan (several modifications)	Sent to 1 manufacturer, SAG and public consultation for comments with deadline 12/06/2013.
V4	05/07/13	KBF/ TR	Fourth version of project plan (major modifications)	Sent to Co-Lead partner (LBI-HTA) for comments.
V5	12/07/13	KBF/ TR	Fifth version of project plan (minor modifications)	Sent to the two manufacturers not represented in SAG for comments, and to the three other manufacturers, co-authors and reviewers for information.
V6	14/08/13	KBF/ TR	Sixth final version	Sent for publication on EUnetHTA website
V7	12/09/13	KBF/ TR	Modification of final version	Identification of three further manufacturers of potentially relevant RDN devices. Sent to them for information.

A. PROJECT PLAN

1.0 PARTICIPANTS

Table 1: Project participants

#	Name	Initials	Role in the project	Agency	Country
1.	Katrine B. Frønsdal	KBF	Author	NOKC	Norway
2.	Tove Ringerike	TR	Author	NOKC	Norway
3.	Leonor Varela Lema	LVL	Co-Author	Avalia-t	Spain
4.	Gerardo Atienza Merino	GAM	Co-Author	Avalia-t	Spain
5.	Karla Douw	KD	Co-Author	CR.DK	Denmark
6.	Claus Løvschall	CL	Co-Author	CR.DK	Denmark
7.	Karen MacPherson	KM	Reviewer	Healthcare Improvement Scotland	United Kingdom
8.	Susan Myles	SM	Reviewer	Healthcare Improvement Scotland	United Kingdom
9.	Neill Booth	NB	Reviewer	FINOHTA/THL	Finland
10.	Sinikka Sihvo	SIS	Reviewer	FINOHTA/THL	Finland
11.	Aleksandra Pelczarska	AP	Reviewer	AHTAPol	Poland
12.	Urszula Cegłowska	UC	Reviewer	AHTAPol	Poland
13.	Anna Zawada	AZ	Reviewer	AHTAPol	Poland
14.	Zoltan Huszti	ZH	Reviewer	GYEMSZI	Hungary

15.	Stefan Sauerland	STS	Reviewer	IQWIG	Germany
16.	Jan Erik Nordrehaug	JEN	External Reviewer 1 (Cardiovascular specialist)	Haukeland University Hospital, Bergen	Norway
17.	To be determined (TBD)	TBD	External Reviewer 2	TBD	Europe

1.1 PROJECT STAKEHOLDERS

Table 2: Project stakeholders

Organisation	**Contact (name, e-mail, tel)**	**Comments**
Medtronic Vascular (Symplicity™ System)	Mitch Sugarman, e-mail: mitchell.sugarman@medtronic.com, tel: +1 707 591-2180 Bonnie Handke, e-mail: bonnie.handke@medtronic.com, tel: +1 707 591-2180 Sid Cohen, e-mail: sidney.cohen@medtronic.com, tel: +1 707 591-2180	
Covidien (OneShot™ System)	Matthieu Cuche, e-mail: matthieu.cuche@covidien.com, tel: +41 79 847 85 49	
St. Jude Medical (EnligHTN™ System)	Sebastian Gaiser, e-mail: sgaiser@sjm.com, tel: : +32 499 544 103	
Boston Scientific (Vessix V2™ System)	Lisa Da Deppo, e-mail: Lisa.DaDeppo@bsci.com; tel: +39 340 346 5544 Jeannette Bankes, email: Jeannette.Bankes@bsci.com; tel: +1 763-255-0001 Yahia Tahiri, e-mail: TahiriY@bsci.com; tel: +33 6 07 167012	
ReCor Medical (Paradise™ System)	The manufacturer was contacted via E-Mail on the 12th of July 2013 and the 15th of July 2013 and was invited to provide comments on the Draft Project	No response received

	Plan and evidence on the Paradise™ System.	
Medtronic (MarinR®)	Bonnie Handke, e-mail: bonnie.handke@medtronic.com, tel: +1 707 591-2180 The manufacturer was contacted via E-Mail on the 13th of September 2013 and was invited to provide evidence on the Marinr® catheter. The Project Plan was submitted.	
Biosense Webster (J&J) (Celcius® and Navistar® ThermoCool®)	The manufacturer was contacted via E-Mail on the 13th of September 2013 and was invited to provide evidence on the Celcius® and Navistar® ThermoCool® catheter. The Project Plan was submitted.	No response received
Terumo (Iberis® System)	The manufacturer was contacted via E-Mail on the 13th of September 2013 and was invited to provide evidence on the Iberis® System. The Project Plan was submitted.	No response received

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

	Primary 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
2.	To examine whether and how the collaboratively produced assessments are applied at a national/local context	Production of ≥1 national/local report per pilot rapid assessment

This pilot rapid assessment will address the research question whether renal denervation/renal nerve ablation using the products/systems available on the market in patients with treatment-resistant arterial hypertension is more effective and/or safer than standard of care, which includes pharmacological treatment, device-based therapy of hypertension and sham treatment (secondary objective of the project).

A scoping search in Google has identified four recent reviews (NICE 2011; LBI-HTA 2011; Avalia-t 2012; Region Västra Götaland, HTA-centrum 2013). These have served as support for developing the project scope below.

Table 3: Project Scope: PICO

Description	Project scope
Population	Patients with treatment-resistant arterial hypertension (defined as persisting hypertension despite administration of at least three antihypertensive drugs in adequate doses including a diuretic) with blood pressure ≥ 140/90 mm Hg (Calhoun 2008; Mancia 2013) and without secondary cause of hypertension. ICD-10 code: Hypertensive diseases I10 - I15 MeSH terms: Hypertension; Blood Pressure

	Intended use of the technology: treatment
Intervention	Renal nerve ablation/denervation systems. The intervention involves destruction of sympathetic nerve endings within the wall of the renal arteries to reduce sympathetic nerve traffic, thereby causing a reduction in blood pressure. MeSH terms: Denervation; Kidney Catheter Ablation
Comparison	Standard of care (which includes here: pharmacological treatment, device-based therapy of hypertension and sham treatment)
Outcomes	Primary outcomes: Overall mortality Cardiovascular mortality Cardiovascular morbidity (stroke, myocardial infarction, heart failure) Blood pressure (changes of systolic and diastolic blood pressure) Complications during or after the treatment Secondary outcomes: Left ventricular hypertrophy/Systolic and diastolic cardiac function

	Kidney function
Study design	Efficacy/effectiveness: Systematic reviews/HTAs, randomized controlled trials (RCTs) and, if data from randomized controlled trials are lacking or insufficient, prospective, controlled studies Safety: As for efficacy but also all prospective studies
Languages	English, Spanish, French, German, Swedish, Danish, Norwegian

Inclusion criteria are defined by the Population-Intervention-Control-Outcome (PICO), study design and languages described in the table above. Included literature in languages other than English will be translated. Exclusion criteria are pure cost-effectiveness studies.

4.0 PROJECT APPROACH AND METHOD

Table 4: Project approach and method

Project approach and method
Overall project process: This rapid assessment will be based primarily on a basic systematic literature search in the following sources: • Biomedical databases (Medline via Ovid, Embase) • Cochrane database, DARE and HTA databases via the Cochrane Library and CRD • The ISI database • In addition, we will use the WHO search portal International Clinical Trials Registry Platform (ICTRP) to identify registered clinical trials. • Information from the manufacturers Relevant articles for the four domains will be selected by the agency who will answer research questions of the domain they are primarily responsible for (see section “Responsibilities and distribution of work among authors and co-authors” below). References

will be included or excluded according to the PICO-scheme described above. In terms of study design, systematic reviews/HTAs, randomized controlled trials (RCTs) and, if data from randomized controlled trials are lacking or insufficient, prospective, controlled studies are selected for answering questions related to the domain "clinical effectiveness", while for questions in the "safety domain" any prospective study will be included. For the two other domains ("Health problem and current use of the technology" and "Description and technical characteristics"), no restrictions in terms of study design will be applied.

In cases where questions within the domains "Health problem and current use of technology" and "Description and technical characteristics of technology" and "Safety" cannot be answered using the information retrieved from the basic systematic literature search described above, additional searches within specific information sources (e.g. databases for clinical guidelines, registries etc.) and, if needed, hand searching will be performed.

For assessing the quality of systematic reviews (SR), the English version of the NOKC checklist for systematic reviews adapted from the Cochrane EPOC group appraisal list for systematic reviews (Grimshaw 2003) will be used (NOKC SR checklist 2013). SRs of high quality will be included. Quality of studies will be assessed using Cochrane risk of bias (RoB) checklist for randomised controlled trials (RCTs) and checklist for non-randomised studies (Higgins 2011).

From the selected studies (including ongoing studies identified from the trial registry searches), study characteristics, results concerning efficacy/effectiveness and safety will be extracted into a data extraction table covering the elements described in the table below. Efficacy and safety will be assessed by using the GRADE-instrument as this methodology allows for a transparent summary of the evidence in a qualitative manner (GRADE 2004). All reporting of clinical effectiveness and safety data will be done according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA Statement 2012).

Responsibilities and distribution of work between authors (NOKC) and co-authors (Avalia-t and CR.DK):

NOKC is author of review and responsible for coordinating the work. NOKC' specific tasks are to:

- Develop the first draft the project plan
- Involve clinical expert(s)
- Develop a scientific process plan with specific tasks to be carried out, time frames and deadlines of milestones and deliverables (below)
- Perform the basic literature search
- Carry out the assessment of "Clinical effectiveness" of the review

- Perform assessments of ethical and organisational aspects if needed
- Review assessments of the two co-authors
- Send "final versions" to reviewers, compile feedback from reviewers and stakeholders as well as changes made according reviewers and stakeholders' comments
- Compile all domains into a final report and write a final summary of the review

Avalia-t is co-author of the review. Avalia-t's specific tasks are to:

- Review draft project plan
- Carry out the assessment of "Safety" of the review, which includes performing additional searches if needed
- Review assessments of the other two authors
- Review final version of the review

CR.DK is co-author of the review. CR.DK's specific tasks are to:

- Review draft the project plan
- Prepare the "Health problem and current use of the technology" and "Description and technical characteristics" domains of the review, which includes performing additional searches if needed
- Review assessments of the other two authors
- Review final version of the review

Table 5: Preliminary Evidence

Preliminary evidence table
Author, year, reference number
Country
Sponsor
Intervention/product

Comparator
Study design
Number of patients
Patient characteristics: age, sex, current treatment, blood pressure, etc.
Author disclosure (Conflict of interest)
Follow-up (months, years)
Loss-to-follow-up, n (%)
Efficacy outcomes
Overall mortality
Cardiovascular mortality
Cardiovascular morbidity
Kidney function
Blood pressure (changes short- and long term of systolic and diastolic blood pressure)
Left ventricular hypertrophy/Systolic and diastolic cardiac function
Complications during or after the treatment
Safety outcomes
Adverse events (AE) in n (%) of patients
Description of AE in n (%) of patients
Serious adverse events (SAE) in n (%) of patients

Description of SAE in n (%) of patients

Selected assessment elements:

The table shows the assessment elements and the translated research questions that will be addressed in the assessment. They are based on the assessments elements contained in the document "Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals". Additionally, assessment elements from other EUnetHTA Core Model Applications (for medical and surgical interventions, for diagnostic technologies or for screening) have been screened and included/merged with the existing questions if deemed relevant.

Table 6: Assessment elements and translating research questions

ID	Domain	Topic	Issue	Source of assessment element	Relevance in this assessment Yes/No	Preliminary research question(s) or Reason for non-relevance/
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?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the precise definition of treatment-resistant arterial hypertension and which diagnosis is given according to ICD-10?
A0003	Health Problem and Current Use of the Technology	Target Condition	What are the known risk factors for the condition?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What are the known risk factors for treatment-resistant arterial hypertension?
A0004	Health Problem and Current Use of the Technology	Target Condition	What is the natural course of the condition?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the natural course of treatment-resistant arterial hypertension?

A0005	Health Problem and Current Use of the Technology	Target Condition	What is the burden of disease for the patient?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the burden of treatment-resistant arterial hypertension for the patient?
A0006	Health Problem and Current Use of the Technology	Target Condition	What is the burden of the disease for society?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the burden of treatment-resistant arterial hypertension for society in terms of prevalence, incidence and costs?
A0007	Health Problem and Current Use of the Technology	Target Population	What is the target population in this assessment?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	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?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	No	This is mainly required for budget impact analysis, which is outside the scope of the assessment (partly covered by A006)
A0001	Health Problem and Current Use of the Technology	Utilisation	For which health conditions and populations, and for what purposes is the technology used?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	For which indication or for what purposes is renal denervation used, and are there any contra-indications?
A0011	Health Problem and Current Use of the Technology	Utilisation	How much are the technologies utilised?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the expected annual utilization of renal denervation?
A0024	Health Problem and Current Use of the Technology	Current Management of the	How is the health condition currently diagnosed according to published	Model for Rapid Relative Effectiveness Assessment of	Yes	How is treatment-resistant arterial hypertension currently diagnosed according to

		Condition	guidelines and in practice?	Pharmaceuticals		published guidelines and in practice?
A0020	Health Problem and Current Use of the Technology	Regulatory Status	What is the marketing authorisation status of the technology?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the marketing authorisation status of renal denervation systems?
A0021	Health Problem and Current Use of the Technology	Regulatory Status	What is the reimbursement status of the technology?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the reimbursement status of renal denervation systems?
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)?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is renal denervation 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)?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the approved indication and claimed benefit of renal denervation 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)?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the phase of development and implementation of renal denervation systems 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)?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	Who performs or administers renal denervation 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?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	In what context and level of care are renal denervation systems and the treatment alternatives?
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)?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What kind of special premises are needed to use renal denervation systems and 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?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What materials are needed to use renal denervation systems and the treatment alternatives?
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?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What kind of data and records are needed to monitor the renal denervation systems and the 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?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What kind of registry is needed to monitor the use renal denervation systems and treatment alternatives?
Safety						
C0001	Safety	Patient safety	What kind of harms can use of the technology cause to the patient?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What are the adverse events and serious adverse events in patients treated with renal denervation?

C0002	Safety	Patient safety	What is the dose relationship of the harms?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	Are there any dose relationship of the harms (e.g. intensity, length of treatment)?
C0004	Safety	Patient safety	How does the frequency or severity of harms change over time or in different settings?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What are the potential short- and long term harms, their frequency, and differences according to settings?
C0005	Safety	Patient safety	What are the susceptible patient groups that are more likely to be harmed?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	Are there any susceptible patient groups more likely to be harmed?
C0007	Safety	Patient safety	What are the user-dependent harms?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	Can adverse events be caused by the behaviour of patients, professionals or manufacturers?
C0008	Safety	Patient safety	How safe is the technology in relation to the comparator?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the safety of renal denervation in relation to standard of care (which includes additional pharmacological treatment, device based therapy of hypertension and sham treatment)?
C0040	Safety	Environmental safety	What kind of harms are there for public and environment?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	No	Not relevant for the technology
Clinical effectiveness						

D0001	Clinical effectiveness	Mortality	What is the expected beneficial effect of the intervention on overall mortality?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the effect of renal denervation on overall mortality?
D0002	Clinical effectiveness	Mortality	What is the expected beneficial effect on the disease-specific mortality?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the effect of renal denervation on cardiovascular mortality?
D0003	Clinical effectiveness	Mortality	What is the effect of the intervention on the mortality due to causes other than the target disease?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	No	Mortality due to causes other than cardiovascular disease will be apparent as part of overall mortality.
D0005	Clinical effectiveness	Morbidity	How does the technology affect symptoms and findings?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	How does renal denervation affect symptoms and findings?
D0006	Clinical effectiveness	Morbidity	How does the technology affect progression of disease?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	How does renal denervation affect progression of treatment-resistant arterial hypertension?
D0008*	Clinical Effectiveness	Morbidity	What is the rate of direct morbidity related to the use of the technology?	HTA Core Model for Medical and Surgical Interventions	No	Addressed in C001
D0011	Clinical effectiveness	Function	What is the effect of the technology on patients' body functions?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the effect of renal denervation on patients' body functions (e.g. kidney function)?
D0016	Clinical effectiveness	Function	How does the use of technology affect activities	Model for Rapid Relative Effectiveness Assessment of	Yes	How does the use of renal denervation affect

			of daily living?	Pharmaceuticals		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?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the effect of renal denervation on generic health-related quality of life?
D0013	Clinical effectiveness	Health-related quality of life	What is the effect of the technology on disease-specific quality of life?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	What is the effect of renal denervation on disease-specific quality of life?
D0017	Clinical effectiveness	Patient satisfaction	Was the use of the technology worthwhile?	Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals	Yes	Were patients overall satisfied with renal denervation?
D0018*	Clinical Effectiveness	Patient satisfaction	Is the patient willing to use the technology?	HTA Core Model for Medical and Surgical Interventions	Yes	Would the patient be willing to undergo renal denervation?
D0023*	Clinical Effectiveness	Change in management	How does the technology modify the need for other technologies and use of resources?	HTA Core Model for Diagnostic Technologies	Yes	How does renal denervation modify the need for other technologies and use of resources?

* These assessment elements were added since they were included in the first pilot (EndoBarrier™)

Checklist for potential ethical, organisational, social and legal aspects

The following checklist should be considered in order to determine whether there are specific ethical, organisational, social and legal aspects which also need to be addressed. Since the assessment is comparative in nature, only new issues should be dealt with, which arise from a difference between the technology to be assessed and its major comparator(s). Already known problems/issues with regard to ethical,

organisational, social and legal aspects which are common to the technology to be assessed and its comparator(s) will, as a rule, not be addressed, as it is not to be expected that the addition of a new technology will lead to changes. If a question is answered with 'yes', further analysis of these issues may be warranted. If they are answered with no, the domains need not be dealt with further.

Table 7: Checklist for potential ethical, organisational, social and legal aspects

1. Ethical	
1.1. Does the introduction of renal denervation and its potential use/nonuse instead of the defined, existing comparator(s) give rise to any new ethical issues (equal access to the treatment, resource allocation/shortage etc.)?	Yes
1.2. Does comparing renal denervation to the defined, existing comparators point to any differences which may be ethically relevant?	No
2. Organisational	
2.1. Does the introduction of renal denervation and its potential use/nonuse instead of the defined, existing comparators require organisational changes in terms of training in procedure, need for facilities, equipment and resources?	Yes
2.2. Does comparing renal denervation to the defined, existing comparators point to any differences which may be organisationally relevant (e.g. shift from primary to secondary care, transportation, etc.)?	Yes
3. **Social**	
3.1. Does the introduction of renal denervation and its potential use/nonuse instead of the defined, existing comparator(s) give rise to any new social issues?	No
3.2. Does comparing renal denervation to the defined, existing comparators point to any differences which may be socially relevant?	No
4. **Legal**	
4.1. Does the introduction of renal denervation and its potential use/nonuse instead of the defined, existing comparator(s) give rise to any legal issues?	No
4.2. Does comparing renal denervation 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 8: Milestones and Deliverables

Milestones/Deliverables	Start date	End date
Project duration	01/03/2013	17/12/2013
Pilot team building	01/03/2013	30/04/2013
Scoping phase	01/03/2013	12/08/2013
Consultation of draft project plan with co-authors	10/05/2013	15/05/2013
Consultation of draft project plan with dedicated reviewers	16/05/2013	23/05/2013
Contact with 1 manufacturer (draft Project Plan, request for further information)	28/05/2013	12/06/2013
Consultation of draft Project Plan (public consultation, SAG, SF)	28/05/2013	12/06/2013
Contact with further manufacturers (draft Project Plan, request for further information)	15/07/2013	05/08/2013
Final Project Plan	05/08/2013	12/08/2013
Assessment phase	12/08/2013	17/12/2013
First draft available		04/10/2013
Review by dedicated reviewers	07/10/2013	21/10/2013
Second draft available		25/10/2013

Review by ≥ 2 external clinical experts, manufacturer(s) and by Strand B members	28/10/2013	18/11/2013
Third draft available		29/11/2013
Medical editing	29/11/2013	06/12/2013
Final pilot rapid assessment (including formatting)		17/12/2013
Local Reports (if applicable)		
Local (national or regional) REA N°1 [*NOKC, Norway*]	Spring 2014	Fall 2014
Local (national or regional) REA N°2 [*IQWIG, Germany*]	Fall 2013	End 2013/beginning 2014

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 9: Communication

Communication Type	Description	Date	Format	Participants/ Distribution
Draft Project Plan with timelines	Review of methods and assessment elements chosen, discussion of time-lines	23/05/2013	E-mail exchange (e-meetings – if required)	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 Forum, public, manufacturer	12/08/2013	E-mail exchange (e-meetings – if required)	Author(s), Co-author(s), dedicated reviewers, Coordinating Team
First draft of the pilot assessment	To be reviewed by dedicated reviewers	04/10/2013	E-mail exchange (e-meetings – if required)	Dedicated reviewers
	To discuss comments of dedicated reviewers (optional)	21/10/2013-25/10/2013	E-mail exchange (e-meetings – if required)	Author(s), co-author(s), dedicated reviewers
Second draft of the pilot assessment	To be consulted with ≥1 clinical expert, WP5 members, other potential stakeholders, manufacturer(s)	25/10/2013	E-mail exchange (e-meetings – if required)	≥1 clinical expert, WP5 members, other potential stakeholders, manufacturer(s)

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

The WP5 SAG as well as the public will be invited to comment on the draft Project Plan for this pilot rapid assessment. The draft Project Plan will be made publicly available on the EUnetHTA website for a period of 10 days. The manufacturers will also receive the draft Project Plan and will be asked for further information (e.g. C/E mark, on-going studies, available evidence).

8.0 COLLABORATION WITH EUnetHTA WPs

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

9.0 RESOURCE PLANNING

(see table below).

10.0 HUMAN RESOURCES

Table 10: 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(s)	10 person days each	-	10 person days each
Medical Editor	5 person days	-	5 person days
Formatting	3 person days	-	3 person days

11.0 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.

12.0 EXPECTED OUTCOME(S)

Project outcome(s)
The capacity of national HTA bodies to collaboratively produce structured rapid core HTA and the translation into local reports will have been proven. Redundancies will have been reduced and therefore efficiency gains achieved. Applicability of the HTA Core Model for rapid REAs to other technologies will have been elicited and the Model accordingly adapted.

B. REFERENCES

Avalia-t (Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia).Renal sympathetic denervation using endovascular radiofrequency ablation for the management of resistant hypertension. Atienza Merino G, Maceira Rozas, C.2012. Available from http://www.sergas.es/Docs/Avalia-t/avalia-t201208DenervacionRenal.pdf (accessed May 2013).

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