EUnetHTA Joint Action 3 2016-2020

Bioresorbable Stents in cardiovascular indications (coronary artery disease)

Project ID: ***OTCA16***

Project description and planning

Institute for General Practice and Evidence-based Health Service Research (IAMEV), Medical University of Graz, Austria

National School of Public Health, Management and Professional Development Bucharest (SNSPMPDSB), Romania

Version Log

Version number	Date	Modification	Reason for the modification
V1	15/06/18	1st version of draft project plan	-
V2	27/06/18	Revised 2nd draft project plan	After comments from dedicated reviewers and SABA e-meeting/discussion with co-authors and dedicated reviewers
V3	03/08/18	Final draft	After comments from external experts

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1 Project organisation

1.1 Participants

Table 1-1: Project participants

	Agency	Role in the project	Country	Distribution of work
Assessment team				
1.	Institute for General Practice and Evidence-based Health Service Research (IAMEV)	Author	Austria	Develop first draft of the project plan. Perform the literature search. Carry out the assessment: select and answer assessment elements, fill in the checklist on potential "ethical, organisational, patient and social and legal aspects" of the HTA Core Model ® for rapid REA. Send "draft versions" to reviewers for comments, compile feedback from reviewers and incorporate relevant changes to the draft. Prepare final assessment including an executive summary.
2.	National School of Public Health, Management and Professional (SNSPMS)	Co-Author	Romania	Review the project plan draft. Support the production of all domains and quality check the steps of their production (data, information, sources). Contribute in answering questions related to potential ethical, organisational, patient, social, and legal aspects if needed. Approve/endorse conclusions drawn as well as all draft versions and the final assessment including the executive summary.
3.	French National Authority for Health (HAS)	Dedicated Reviewer	France	Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts. Review methods, results, and conclusions based on the original studies included. Provide constructive comments in all the project phases
4.	Health Service of Canary Islands (SESCS)	Dedicated Reviewer	Spain	Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts. Review methods, results, and conclusions based on the original studies included. Provide constructive comments in all the project phases
Contributors				
5.	Priv.Doz.Dr. Schuchlenz Herwig	External expert	Austria	• Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts. • Review methods, results, and conclusions based on the original studies included. Provide constructive comments in all project phases.

6.	TBD	External expert		• Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts. • Review methods, results, and conclusions based on the original studies included. Provide constructive comments in all project phases.
7.	Compuscript Ltd.	Medical Editor	Ireland	Medical editing
8.	Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA)	Project Manager	Austria	Project Management

1.2 Project stakeholders

Table 1-2: Project stakeholders

Organisation	Role in the project
Abbott Vascular, Santa Clara, CA, USA - ABSORB	marketing authorisation holder (MAH)
Elixir Medical Corporation, Sunnyvale, CA, USA - DESOLVE	marketing authorisation holder (MAH)
Arterial Remodeling Technologies, France and Franklin Township, NJ, USA – ART Pure (ART18Z)	marketing authorisation holder (MAH)
Reva Medical, San Diego, CA, USA - FANTOM	marketing authorisation holder (MAH)
Biotronik, Bülach, Switzerland - MAGMARIS (DREAMS)	marketing authorisation holder (MAH)
Cardionovum Corporate, Bonn, Germany - XLIMUS DES	marketing authorisation holder (MAH)
TBD	Patient representative
TBD	Patient representative

1.3 Milestones and Deliverables

Table 1-3: Milestones and Deliverables

Milestones/Deliverables	Start date	End date
Project duration	**29/05/2018**	**21/12/2018**
Scoping phase	29/05/2018	31/07/2018
Identification of manufacturer(s) and external experts; *optional: identification of patients*	29/05/2018	15/06/2018
Scoping and development of draft Project Plan incl. preliminary PICO	29/05/2018	15/06/2018
Share the preliminary PICO with external experts for comments	14/06/2018	22/06/2018
Internal Scoping e-meeting with the assessment team	25/06/2018	25/06/2018
Send the preliminary PICO for comments (in case there is no scoping meeting planned) and the request for the completion of the Submission file template to manufacturer(s) (optional)	*25/06/2018*	*29/06/2018*
Contact patient organisations - send and get back patient input template; share the preliminary PICO with patient organisations for comments	26/06/2018	06/07/2018

Consultation of draft Project Plan with dedicated reviewers	29/06/2018	06/07/2018
Consultation of draft Project Plan with external experts *(and patients)* and fact check by manufacturers	13/07/2018	22/07/2018
Amendment of draft Project Plan & final Project Plan available	23/07/2018	10/08//2018
Completion of Submission file template by manufacturer(s) + Clarifying further questions concerning draft Submission file) (optional)	*29/06/2018*	*27/07/2018*
Assessment phase	11/08/2018	31/12/2018
Writing first draft rapid assessment	11/08/2018	03/10/2018
Review by dedicated reviewer(s)	04/10/2018	18/10/2018
Writing second draft rapid assessment	19/10/2018	31/10/2018
Review by ≥ 2 external clinical experts and fact check by manufacturers	02/11/2018	15/11/2018
Writing third draft rapid assessment	15/11/2018	23/11/2018
Medical editing	23/11/2018	07/12/2018
Writing of fourth version of rapid assessment	10/12/2018	14/12/2018
Formatting	14/12/2018	21/12/2018
Final version of rapid assessment		week from 17/12/2018 - to 21/12/2018

2 Project Outline

2.1 Project Objectives

The rationale of this assessment is to collaboratively produce structured (rapid) core HTA information on other technologies. In addition, the aim is to apply those collaboratively produced assessments in the national or regional context.

Table 2-1: Project objectives

	List of project objectives	Indicator (and target)
1.	To jointly produce health technology assessments that are fit for purpose, of high quality, of timely availability, and cover the whole range of health technologies.	Production of 1 (rapid) relative effectiveness assessment.
2.	To apply this collaboratively produced assessment into local (e.g. regional or national) context.	Production of ≥2 local (e.g. national or regional) reports based on the jointly produced assessment.

This rapid assessment addresses the research question whether percutaneous coronary intervention (PCI) with implantation of a fully bioabsorbable/biodegradable/bioresorbable vascular scaffold/stent (BVS) in adult patients with coronary artery disease (CAD) including stable angina, unstable angina, myocardial infarction (ICD-10 code I20-I25) who require and are eligible for myocardial revascularisation is more effective and/or safer than PCI with implantation of other stent types or other revascularisation strategies. This topic was chosen based on a request from the Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection who commissioned our agency to do an HTA on percutaneous coronary intervention (PCI) with implantation of a fully bioabsorbable/biodegradable/bioresorbable vascular scaffold/stent (BVS). The relevance of the topic lies in the fact that CAD, which is a manifestation of atherosclerosis of the coronary arteries, belongs to the most prevalent diseases and it is the leading cause of death in Europe [1].

2.2 Project Method and Scope

2.2.1 Approach and Method

Table 2-2: Project approach and method

Project approach and method
The HTA Core Model Application for rapid Relative Effectiveness Assessment (REA) (4.2) will be the primary source for selecting assessment elements. The selected assessment element generic questions will be translated into research questions. For Description and technical characteristics of technology (TEC) and Health problem and current use of technology (CUR) domains a descriptive analyses will be performed, based on information from different sources: • Input from manufacturers, particularly related to questions on CE mark, marketing, availability and current use. The Medical Devices Evidence Submission template will be sent to all relevant manufacturers of the technology under assessment. Manufacturers will be asked to submit non-confidential documents, focusing on the technical characteristics and current use of the technology and on unpublished trial results. • Input from clinical experts, particularly related to description of disease, current treatment, current use and best available epidemiological data. The clinical experts will be asked to

verify the relevance and accuracy of the information and citations.
- Clinical guidelines: A search for current clinical guidelines in the Guidelines International database (G-I-N) will be performed by the author.
- Relevant literature identified by the literature search for the EFF and SAF domains.

No quality assessment of the included literature will be conducted for these two domains.

For Effectiveness (EFF) and Safety (SAF) domains, we will perform a systematic literature search. The author and co-author will independently screen the titles and abstracts and select studies according to the pre-defined inclusion and exclusion criteria. The full-text publications will be retrieved by the author and the full-text examination will be performed by the author and the co-author independently. The author will provide a list of included and excluded studies. Discrepancies will be resolved by discussion or with the help of a third party (dedicated reviewers).
The Risk of bias (RoB) assessment of the included studies will be done according to the Cochrane Risk of bias tool [2] on study and outcome level. The 'Risk of bias' of each included trial will be assessed by the author and the co-author independently. Any disagreements will be resolved by consensus or by consulting a third party (dedicated reviewers). The strength of evidence for all critical outcomes will be rated according to GRADE (Grading of Recommendations Assessment, Development and Evaluation) scheme [3], which takes into account issues related not only to internal validity (risk of bias, inconsistency, imprecision, publication bias) but also to external validity, such as directness of results. The results of the rating will be presented in GRADE Summary of Findings (SoF) tables. The author will perform the GRADE rating and the co-author will check it. Disagreements will be resolved by consensus.

Table 2-3: Planned literature search strategy

Literature search strategy
For Effectiveness (EFF) and Safety (SAF) domains, we will perform a systematic literature search in the bibliographic databases PubMed, MEDLINE, EMBASE and Cochrane Central Register of Controlled Trials and Cochrane Database for Systematic Reviews, according to the predefined search strategy. Furthermore, a search in the clinical trials registries ClinicalTrials.gov and WHO-ICTRP will be carried out for ongoing studies. In addition to the electronic search, we will review the references from relevant original articles and reviews. Search terms: MeSH or text words for “stable angina”, “unstable angina”, “myocardial infarction”, “coronary artery disease, “heart disease” using word variations COMBINED with MeSH or text words for “bioabsorbable”, “biodegradable” using word variations AND with MeSH or text words for “percutaneous coronary interventions”, “stent”, “scaffold” using word variations OR product names (Absorb, DESolve, MAGMARIS (DREAMS), ART Pure (ART18Z), Fantom, Xlimus) Inclusion criteria: According to the PICO question summarized in table 2-5 Exclusion criteria: language other than English, Spanish, French or German; retrospective study design; less than 50 patients in prospective single-arm cohort studies

Table 2-4: Plan for data extraction

Planned data extraction
Following data will be extracted from the included studies: • Study characteristics (authors, year of publication, setting/country, objective, inclusion

criteria, study design, study duration, primary study endpoint, clinical trial identification number/ registry identifier and funding source)
- Participant/patient characteristics (number of participants in the trial, age, sex, condition, anti-platelet co-therapy)
- Intervention and control characteristics (name/type of the device, comparator, description of procedure, length of follow up and loss to follow up)
- Outcomes (Effectiveness endpoints: All-cause mortality, cardiac mortality, cardiovascular morbidity, MACE, HrQoL, target vessel revascularisation, target lesion revascularisation, duration of procedure; Safety endpoints: mortality, serious adverse events (late/very late scaffold/stent thrombosis and its consequences, bleeding from anti-platelet therapy, periprocedural myocardial infarction or mortality, mortality from bleeding/stroke, stenosis, other serious adverse events), adverse events (vascular access-site complication; procedure-related contrast-induced nephropathy)

When at least two included randomised controlled trials (RCTs) are available for a comparison and a given outcome, we will perform meta-analysis using the Cochrane Review Manager software, Review Manager 5.3 [4]. We will perform separate analyses for each type of comparator (drug eluting stents, bare metal stents, etc.). Analyses combining all types of comparators are not planned since the comparative interventions are clinical heterogeneous.

If possible, following subgroup analyses will be performed especially for the critical outcomes:
- type of eluted drug
- indication for stent implantation (stable/unstable condition)
- type of antiplatelet therapy after stent implantation

Since ABSORB Bioresorbable Vascular Scaffold (Abbott Vascular) is currently not available (sales stop in September 2017 due to low commercial sales), sensitivity analyses excluding the ABSORB device, will be performed for the critical outcomes in order to explore its influence on effect size.

Dichotomous data will be expressed as a risk ratio (RR) or odds ratio (OR) with 95% confidence interval (CI). For continuous outcomes measured on the same scale we will estimate the intervention effect using the mean difference with 95% CI. For continuous outcomes that measure the same underlying concept (e.g. health-related quality of life) but use different measurement scales, we will calculate the standardised mean difference (SMD).

If possible, we obtain relevant missing data from the authors of the included trials. We carefully evaluate important numerical data such as screened, randomised assigned participants as well as intention-to-treat (ITT), and as-treated and per-protocol populations. We investigate attrition rates (e.g. drop-outs, losses to follow-up, withdrawals), and we critically appraise issues of missing data and imputation methods (e.g. last observation carried forward (LOCF)).

Where included trials did not report means and SDs for outcomes and we did not receive the necessary information from trial authors, we impute these values by estimating the mean and variance from the median, range, and the size of the sample [5].

2.2.2 Project Scope

Table 2-5: Project Scope: PICO (please see HTA Core Model® for rapid REA)

Description	Project Scope
Population	Adult patients with CAD including stable angina, unstable angina, myocardial infarction (ICD-10 code I20-I25) who require and are eligible for myocardial revascularisation *MeSH-terms: Heart Disease [C14.280], Myocardial Ischemia [C14.280.647], Acute Coronary Syndrome [C14.280.674.124] Angina Pectoris [C14.280.647.124], Coronary Disease [C14.280.647.250], Coronary Artery Disease [C14.280.64], Myocardial Infarction [C14.280.674.7.250.260]*
Intervention	Percutaneous coronary intervention (PCI) with implantation of a fully bioabsorbable/biodegradable/bioresorbable vascular scaffold/stent (BVS) Product names: Absorb, DESolve, MAGMARIS (DREAMS), ART Pure (ART18Z), Fantom, Xlimus Trials: ABSORB, BIOSOLVE, DESolve Nx-Trial, ARTDIVA, RESTORE *MeSH terms: Percutaneous Coronary Intervention [E04.100.814.529.968], Stents [E07.695.750], Drug-Eluting Stents [E07.695.750.500]*
Comparison	PCI with implantation of other stent types or other revascularisation strategies *MeSH-terms: Percutaneous Coronary Intervention [E04.100.814.529.968], Stents [E07.695.750], Drug-Eluting Stents [E07.695.750.500], Coronary Artery Bypass [E04.100.376.719.332]* Rationale: PCI with implanting a permanent drug eluting or bare metal stents or with a bioresorbable polymer drug eluting stent is currently the main strategy to treat CAD [6-8]; another alternative for revascularisation is coronary artery bypass grafting (CABG), which may result in more complete revascularisation, yet with a higher procedural risk [6-8].
Outcomes	**<u>Effectiveness:</u>** **Clinical endpoints** • Mortality (cardiac, all-cause) • Morbidity: angina, myocardial infarction • Quality of life • Daily functioning **Composite endpoints:** • Major adverse cardiac events (MACE) **Surrogate endpoints:** • Re-vascularisation: target vessel revascularisation (TVR), target lesion revascularisation (TLR) **Other endpoints:** • Duration of the procedure **Long-term results** • ≥ 3 years of follow-up Rationale: CAD is associated with an increased risk of mortality and with impaired quality of life, reduced physical endurance, mental depression and recurrent hospitalisation or outpatient visits [8]. Revascularisation should therefore, ideally prolong life expectancy, reduce the symptoms and future revascularisations, and increase health-related quality of life. **<u>Safety:</u>** **Adverse events** • vascular access-site complication • procedure-related contrast-induced nephropathy

	Serious adverse events • late/very late (after ≥ 1 year) scaffold/stent thrombosis and its consequences • bleeding from anti-platelet therapy • periprocedural myocardial infarction or mortality • mortality from bleeding/stroke • other serious adverse events • stenosis **Long-term results** • ≥ 1 year of follow up Rationale: Compared to CABG, PCI + stenting has lower periprocedural risks but bears the risk of late stent thrombosis with potentially severe consequences. Furthermore, the treatment requires long-term anti-platelet therapy, which bears the risk of potentially life-threatening bleeding. Finally, PCI + stenting can be associated with complications at the vascular access site or with nephropathy due to contrast media used in the coronary angiography [9, 10].
Study design	**Effectiveness:** Randomised controlled trials (RCTs) **Safety:** Randomised controlled trials; prospective non-randomised controlled trials; prospective (single-arm) observational studies, e.g. case series, registries with at least 50 patients

3 Communication and collaboration

Table 3-1: Communication

Communication Type	Description	Date	Format	Participants/ Distribution
Scoping	Internal kick-off meeting	29/05/2018	E-meeting	Author(s), co-author(s), dedicated reviewers, project manager
	Scoping e-meeting	25/06/2018	E-meeting	Author(s), co-author(s), dedicated reviewers, project manager
	To internally discuss and reach consensus on the scoping.	15/06/2018-18/07/2018	E-mail	Author(s), co-author(s), dedicated reviewers, project manager, external experts
		as required	*Additional e-meetings may be planned whenever needed*	*Author(s), Co-author(s), dedicated reviewer(s), project manager*
Feedback on draft submission file (optional)	*To point out the requirements for the final submission file by manufacturers*	*[DD/MM/YYYY]*	*E-mail*	*Author(s), project manager, manufacturers*
First draft of the rapid assessment	*To discuss comments of dedicated reviewers*	*[DD/MM/YYYY]*	*E-meetings may be planned*	*Author(s), co-author(s), dedicated reviewers*
Second draft of the rapid assessment	*To discuss comments from ≥ 2 external clinical experts and manufacturers*	*[DD/MM/YYYY]*	*E-meetings may be planned*	*Author(s), co-author(s), dedicated reviewers; external experts, manufacturers*

3.3 Dissemination plan

The final rapid assessment will be published on the EUnetHTA website: http://www.eunethta.eu/joint-assessments.

All stakeholders and contributors are informed about the publication of the final assessment by the project manager.

3.4 Collaboration with stakeholders

Collaboration with manufacturer(s)

There will be a review of the preliminary PICO and a fact check of the 2nd draft project plan and the 2nd draft assessment by the manufacturer(s).

Collaboration with other stakeholders

Patient involvement was planned and umbrella patient organizations (European Heart Network and Heart Failure Association) as well as national patient organizations from Austria, Ireland, UK, France, Finland, Spain, Romania, Germany, Sweden, Belgium and the Netherlands were contacted to provide input on the preliminary PICO and through the HTAi patient input form . However it was not possible to obtain participation, which was hindered by organizational and logistic issues.

3.5 Collaboration with EUnetHTA WPs

For the individual rapid assessment, some collaboration with other WPs is planned: WP7 [Implementation] will be informed of the project, in order to prepare activities to improve national uptake of the final assessment. Feedback on the WP4 REA process will be asked from the

involved parties by WP6 [Quality Management], and this information will be processed by WP6 to improve the quality of the process and output.

3.6 Conflict of interest and confidentiality management

Conflicts of interest will be handled according to the EUnetHTA Conflict of Interest Policy. All individuals participating in this project will sign the standardised "Declaration of Interest and Confidentiality Undertaking" (DOICU) statement.

Authors, co-authors and dedicated reviewers who declare a specific conflict of interest will be excluded from the whole work under this specific topic. However, they still may be included in other assessments.

For external experts, patients or other stakeholders involved, conflict of interest declarations are collected. External experts or patients who declare a specific conflict of interest will be excluded from parts of or the whole work under this specific topic. However, they still may be included in other assessments.

Manufacturer(s) will sign a Confidentiality Undertaking (CU) form regarding the specific project.

4 References

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[6] Ibanez B, James S, Agewall S, et al. 2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: The Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC). Eur Heart J. 2018 Jan 7; 39 (2): 119-77

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[9] Marenzi G, Lauri G, Assanelli E, et al. Contrast-induced nephropathy in patients undergoing primary angioplasty for acute myocardial infarction. J Am Coll Cardiol. 2004 Nov 2; 44 (9): 1780-5

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Feldfunktion geändert

5 Appendix A

5.1 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 assessment elements contained in the 'Model for Rapid Relative Effectiveness Assessment'. Additionally, assessment elements from other HTA 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 5-1: Selected Assessment Elements

ID	Topic	Topic Issue	Relevance in this assessment	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
Description and technical characteristics of technology					
B0001	Features of the technology and comparators	What is the technology and the comparator(s)?	Yes	M	What are fully bioresorbable vascular stents and the comparators (other stent types or other revascularisation strategies)?
A0020	Regulatory Status	For which indications has the technology received marketing authorisation or CE marking?	Yes	M	For which indications have fully bioresorbable vascular stents received marketing authorisation or CE marking?
B0002	Features of the technology and comparators	What is the claimed benefit of the technology in relation to the comparator(s)?	Yes	M	What is the claimed benefit of fully bioresorbable vascular stents in relation to the comparators (other stent types or other revascularisation strategies)?
B0003	Features of the technology	What is the phase of development and implementation of the technology and the comparator(s)?	Yes	NM	What is the phase of development and implementation of fully bioresorbable vascular stents and the comparators (other stent types or other revascularisation strategies)?
B0004	Features of the technology	Who administers the technology and the comparator(s) and in what context and level of care are they provided?	Yes	M	Who administers fully bioresorbable vascular stents and the comparators (other stent types or other revascularisation strategies) and in what context and level of care are they provided?
B0008	Investments and tools required to use the technology	What kind of special premises are needed to use the technology and the comparator(s)?	Yes	NM	What kind of special premises are needed to use fully bioresorbable vascular stents and the (other stent types or other revascularisation strategies)?
B0009	Investments and tools required to use the technology	What equipment and supplies are needed to use the technology and the comparator(s)?	Yes	NM	What equipment and supplies are needed to use fully bioresorbable vascular stents and the comparators (other stent types or other revascularisation strategies)?
A0021	Regulatory Status	What is the reimbursement status of the technology?	Yes	NM	What is the reimbursement status of fully bioresorbable vascular stents?
Health problem and current use of technology					
A0002	Target Condition	What is the disease or health condition in the scope of this assessment?	Yes	M	What is coronary artery disease (CAD)?
A0003	Target Condition	What are the known risk factors for the disease or health	Yes	M	What are the known risk factors for coronary artery disease (CAD)?

ID	Topic	Topic Issue	Relevance in this assessment	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
		condition?			
A0004	Target Condition	What is the natural course of the disease or health condition?	Yes	M	What is the natural course of coronary artery disease (CAD)?
A0005	Target Condition	What are the symptoms and the burden of disease or health condition for the patient?	Yes	M	What are the symptoms and the burden of coronary artery disease (CAD) for the patient?
A0006	Target Condition	What are the consequences of the disease or health condition for the society?	Yes	NM	What are the consequences of coronary artery disease (CAD) for the society?
A0024	Current Management of the Condition	How is the disease or health condition currently diagnosed according to published guidelines and in practice?	Yes	M	How is coronary artery disease (CAD) currently diagnosed according to published guidelines and in practice?
A0025	Current Management of the Condition	How is the disease or health condition currently managed according to published guidelines and in practice?	Yes	M	How is coronary artery disease (CAD) currently managed according to published guidelines and in practice?
A0007	Target Population	What is the target population in this assessment?	Yes	M	What is the target population in this assessment?
A0023	Target Population	How many people belong to the target population?	Yes	M	How many people belong to the target population?
A0011	Utilisation	How much are the technologies utilised?	Yes	M (NM for diagnostics)	How much are fully bioresorbable vascular stents utilised?
Clinical effectiveness					
D0001	Mortality	What is the expected beneficial effect of the intervention on mortality?	Yes	M	What is the expected beneficial effect of fully bioresorbable vascular stents on mortality?
D0005	Morbidity	How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?	Yes	M	How do fully bioresorbable vascular stents affect symptoms and findings (severity, frequency) of coronary artery disease (CAD)?
D0006	Morbidity	How does the technology affect progression (or recurrence) of the disease or health condition?	Yes	M	How do fully bioresorbable vascular stents affect progression (or recurrence) of coronary artery disease (CAD)?
D0011	Function	What is the effect of the technology on patients' body functions?	Yes	M	What is the effect of fully bioresorbable vascular stents on patients' body functions?
D0016	Function	How does the use of technology affect activities of daily living?	Yes	NM	How does the use of fully bioresorbable vascular stents affect activities of daily living?
D0012	Health-related quality of life	What is the effect of the technology on generic health-related quality of life?	Yes	M	What is the effect of fully bioresorbable vascular stents on generic health-related quality of life?
D0013	Health-related quality of life	What is the effect of the technology on disease-specific quality of life?	Yes	M	What is the effect of fully bioresorbable vascular stents on disease-specific quality of life?
D0017	Patient satisfaction	Were patients satisfied with the technology?	No	NM	

ID	Topic	Topic Issue	Relevance in this assessment	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
Safety					
C0008	Patient safety	How safe is the technology in relation to the comparator(s)?	Yes	M	How safe are fully bioresorbable vascular stents in relation to the comparators (other stent types or other revascularisation strategies)?
C0002	Patient safety	Are the harms related to dosage or frequency of applying the technology?	No	NM	
C0004	Patient safety	How does the frequency or severity of harms change over time or in different settings?	Yes	M	How does the frequency or severity of harms change over time or in different settings?
C0005	Patient safety	What are the susceptible patient groups that are more likely to be harmed through the use of the technology?	Yes	M	What are the susceptible patient groups that are more likely to be harmed through the use of fully bioresorbable vascular stents?
C0007	Patient safety	Are the technology and comparator(s) associated with user-dependent harms?	No	NM	
B0010	Safety risk management	What kind of data/records and/or registry is needed to monitor the use of the technology and the comparator(s)?	Yes	M for medical devices NM for screening and diagnostics	What kind of data/records and/or registry is needed to monitor the use of bioresorbable vascular stents and the comparators (other stent types or other revascularisation strategies)?

5.2 Checklist for potential ethical, organisational, patient and social and legal aspects

1. Ethical	
1.1. Does the introduction of the new technology and its potential use/non-use 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 that may be ethically relevant?	No
2. Organisational	
2.1. Does the introduction of the new technology and its potential use/non-use instead of the defined, existing comparator(s) require organisational changes?	No
2.2. Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be organisationally relevant?	No
3. Social	

3.1. Does the introduction of the new technology and its potential use/non-use 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 comparator(s) point to any differences that may be socially relevant?	No
4. Legal	
4.1. Does the introduction of the new technology and its potential use/non-use 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 comparator(s) point to any differences that may be legally relevant?	No