EUnetHTA JA2 WP5 –STRAND B
Public Consultation comments and author's replies on the Draft Project Plan on 'Transcatheter mitral valve repair in adults with chronic mitral valve regurgitation'

The Draft Project Plan on *Transcatheter mitral valve repair in adults with chronic mitral valve regurgitation* was open to public consultation between 30/03/2015 and 22/04/2015.

The aim of the Project Plan is to provide an overview on the planned processes, the scope, the scientific methods and the time-schedule for compiling a Pilot Rapid Assessment on the technology mentioned above. The Pilot Rapid Assessment (partly or as a whole) will be translated into national/local reports by participating WP5 members.

Comments were received from:

Institution	Name	Contact details
Abbott Vascular	Sophie Cros, Director, Market Access & Health Economics, EMEA	Cullinganlaan 2B – 1831 DIEGEM – BELGIUM http://www.abbottvascular.com
Eucomed	Zuzana Pisano, Manager Market Access & Economic Policies	Rue Joseph II 40, 1000 Bruxelles http://www.eucomed.be/

Answered but didn't provide comments:

Institution	Name	Contact details
MINISTRY OF HEALTH OF THE CZECH REPUBLIC	Pharm. Dr.Renata Semeráková	www.mzcr.cz
Cardiac Dimensions	Omari Bouknight	http://www.cardiacdimensions.com

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Summarized comments and replies:

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1	4	1.0 Participants – Table 1	Abbott Vascular	For those comments, we refer to the WP5 Strand B manual (version 3, 29th April 2013) and note the following: Whilst the project is already advanced, we note the second co-author is mentioned as TBD, as well as 2 reviewers and the medical editor. - In the manual, it is indicated that "Reviewers support authors from the very beginning of the project. They will participate during scoping and they will be consulted for the draft Project Plan. They accept the Project Plan and agree on timelines. In cases of disagreement between author(s) and co-author(s), dedicated reviewers will be consulted." We are concerned by the fact that those individuals are not identified at that advanced stage for the project. Could you please comment on that? - What is the role of the medical editor (not explained in the procedure manual of WP5 Strand B (version 3, 29th April 2013)? For instance, how this role differs from the role of external reviewers for which it is indicated Cardiology therefore we suppose that those reviewers are cardiologists. From which area of expertise this expert will come from? - External reviewers: will they be from Scotland and Italy or only Scotland? And how many in total? On that, the manual also indicates the possibility to reach out to physician's societies and patients associations. We notice that there is no mention of this prior to the public consultation. Is this something already on going?	It is not the individual that is mentioned as TBD (to be determined) but the individual's expertise; just the information on the person's background/ expertise apart from HTA methods was missing in the draft version of the project plan. The pilot team was decided on in the very beginning of the project. The medical editor is not decided on at this stage, will be identified later in the project. The procedure manual is currently being updated and the role of the medical editor will be explained in the new version. Medical editors tasks are to check the sense and clarity, internal consistency of terminology and the grammar but they are not involved in compiling the content of the assessments. There are 2 external experts involved, from Italy and Scotland. For identification of these external experts, physician's societies and experts suggested by the SAG and the manufacturers were contacted in October-December 2014. The patient organisations who are members of the Stakeholder Advisory Group of EUnetHTA were contacted but until now, no representative was identified. The inquiry at two other patient organisations was not answered neither.
2	4	Table 1	Eucomed	Eucomed notes that the expertise expected from the 2nd co-author is still to be determined. This is not in line with the WP5 Strand B process manual released in April 2013 which indicates	See answer no.1.

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				on page 8: "Co-authors play a supportive role during the Project Plan development and scoping phase and take active part in the production of pilot rapid assessments". Clarifications on that would be appreciated. Similarly, to our knowledge, the process manual does not mention the role of "medical editor". Explanations on the role and the selection criteria for the medical editor would also be welcome as we would expect that since he is mentioned in the plan he is known and aware of his/her task and demands from the project.	
3	5	Table 2	Abbott Vascular	Project stakeholders contact details should not appear as it was done in previous projects.	Changed.
4	5	Table 2	Eucomed	Eucomed would like to see listed other stakeholders included in the review as we would expect that at this stage of the project they are identified. For example patients (patient groups), physicians (medical societies) as we believe that their involvement is key for any HTA bringing unique type of information and helping to complete the full picture about the technology.	See previous comment.
5	5	Table 2	Eucomed	Eucomed doesn't find it appropriate to make publicly available contact details of the project stakeholders as this might be confidential information and thus we suggest removing it.	See answer no.3.
6	6	Table on line 60 – point 3	Abbott Vascular	Relevance of choice: the statement related to the high cost of the technology "up to 5 times higher than the current treatment options) is not substantiated to our knowledge in the absence of European data on the burden of MR be it treated by drugs or surgery.	This sentence was removed.
7	6	Table last paragraph	Eucomed	"High cost of the technology (up to 5 times higher …..)" We would like to see what is supporting such a statement as we are not aware of any European data on this topic. Also we don't think that this statement can be generalized for Europe however if this is a case for some country we suggest to mention the country.	Please, see reply to comment #6.
8	6	Line 63	Abbott Vascular	We would like to clarify that for the positioning of MitraClip is for non-surgical candidates: Abbott positioning: MitraClip is indicated for patients suffering	We acknowledge MitraClip's positioning.

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				from moderate-to-severe and severe Mitral valve Regurgitation with a high risk or contra-indication for surgery. The first RCT performed with MitraClip therapy was comparing MitraClip to surgery in surgical patients and was reflective of the early experience with the therapy in regards to expertise with the technology and patient selection. Therefore, there is a general agreement amongst clinicians that good surgical candidates should continue to receive surgical intervention. However there is a subset population of patients that are considered as too high risk for surgery in which MitraClip affords a definitive improvement in MR safely and effectively. This is supported by European and US guidelines. When it comes to surgery in DMR, it is worth noting that surgery is recommended in first line despite a low level of evidence (class C).	
9	8	Table – study design	Abbott Vascular	Effectiveness: we understand that prospective registries are part of the Controlled Clinical Trials (CCT).	No, we will not include registries for assessing effectiveness but only comparative studies because of their methodological and scientific robustness.
10	9	Table 4a. Project approach and method	Abbott Vascular	Distribution of tasks among agencies: We reiterate our questions and concerns regarding the 2nd co-author, MoH of Slovakia, and the dedicated reviewers for which some are indicated as TBD in Table 1, page 4 of the document – see comment above. When reading this table, it appears they all have a role and that role is confirmed.	See answer no. 1. It is the expertise that is TBD not the person. All team members are confirmed and actively taking part in the project from the beginning.
11	17	Table 6 – 1. Ethical	Abbott Vascular	Could the authors explicit this concern regarding the ethical issues? We do not think there are ethical concerns related to MitraClip. As explained in our submission, the choice of the therapy is made by a multi-disciplinary team that will address, among other criteria, any possible ethical question. This approach is in line with the European guidelines: "Percutaneous edge-to-edge procedure may be considered in patients with symptomatic severe primary MR who fulfil the echo	We understand your issue. However, we believe that clarifying, in a qualitative way, the ways in which the severity is defined (and the role of the heart team you mentioned) is relevant and should be included in the assessment. We would like to clarify that, according the REA Model methodology, assessment elements within the ethical domain, as well as those within organisational, social, and legal domain, will be just

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				criteria of eligibility, are judged inoperable or at high surgical risk by a 'heart team', and have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C). "	developed qualitatively.
12	18	5.1 Milestones and deliverables – Table 7	Abbott Vascular	Item: Completion of submission file template by manufacturers The time given to manufacturers is considered short for the following reasons: For any submission file related to market access, the internal process Abbott Vascular is following takes into considerations several aspects: - A strategic discussion regarding the dossier and the evidence included in the file. - The time to perform a literature review – if systematic, the time to perform a complete systematic review should be implies delays as it takes at least 3 months. - This process implies that a minimum of 2 drafts before the final file are developed. The review might include external reviewers as well. We understand this project is a pilot therefore we believe it is important to raise this point now to make sure that will be considered in the future.	We acknowledge that the timelines were rather tight. Your concerns will be considered for the evaluation of both the submission file template and WP5B processes.
13	18	Table 7	Eucomed	Eucomed is surprised (and concerned) to see that manufacturers were expected to make a submission before the project plan had been completed, and agreement on PICO reached. It leaves manufacturers at a disadvantage of not knowing exactly what the authors will be looking for.	The preliminary PICO question was sent to manufacturers along with the submission file template to facilitate its completion. We understand this concern and have adapted WP5B processes accordingly.
14	18	Table 7	Eucomed	The timing of the scoping meeting implies it is not a scoping meeting. Scoping normally means it is designed to 'scope out' the remit, identify and agree evidence to be submitted, desired analyses to be undertaken, ensure alignment with process, discuss any specific issues likely to arise. The timing of your scoping meeting reads more like a 'pre-submission' meeting, where fine-tuning can occur. However manufacturers cannot be expected to fine-tune a submission when there has been no	See answer no. 13.

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				agreed scope or even project plan ahead of time. That is unrealistic, and demonstrates a lack of understanding of how submissions are created. We are aware that the issue of timing and scoping has been raised in other WP5A pilots, and the issue acknowledged by EUnetHTA members. It is therefore disappointing to see these same issues perpetuated here.	
15			Eucomed	Looking at the timelines given to manufacturers to complete the submission template (25 working days for the 1st submission taking away Christmas holidays and 10 working days for modifications) we would like to raise several points as we think that such deadlines are too short. • EUnetHTA pilot of REA will most likely not have an immediate effect on the market access of a medical device due to the nature of the medical devices market access model in different countries and role of HTA in it. • Manufacturers involved in EUnetHTA pilots are willing to partner with EUnetHTA to test the European HTA collaboration but would expect that some considerations will be giving to the fact that filing meaningfully submission template takes considerable time and resources. • There are some internal processes that manufacturers need to follow and it demands additional time for completion of such task which should be taken into consideration. As this is a pilot we are raising these points and we would like to discuss about realistic timeframes for manufacturers to complete submission templates so it can be taken into consideration when future REA is prepared.	See answer no. 12.
16	19	Table 7	Abbott Vascular	Local reports: Is it possible to share with the manufacturers the number of local reports foreseen, by which agency and within which timeframe? If not possible at that stage of the project, when could an estimate be provided?	The agencies planning to translate the EUnetHTA assessment into a national report are listed in the project plan (table 7). We can neither confirm the definite uptake nor the timeframe for these national reports. As the EUnetHTA assessment will be finished in September 2015, the confirmation of first national reports cannot be expected before the end

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					of the year.
17	19	Table 7	Eucomed	Eucomed also looks forward to clarification and receiving updates on the list of local reports adaptation as it is not clear what type of adaptation countries are planning and how committed they are.	Please, see reply to comment #16.
18	20	7.0 collaboration with stakeholders	Abbott Vascular	Collaboration with other stakeholders: the manual mentions physicians' societies in addition to patients. Will that be the case? We would strongly recommend it as a good practice principle considering this project is about innovative therapies using first time medical devices. On another hand, health care professionals, and in that case, cardiologists are in charge of the final decision regarding patient selection, as well as delivering the therapy.	See answer no. 1 and 4.
19	GENERAL		Abbott Vascular	We welcome the possibility to comment on the project plan that provides an overview of the project and is a very useful communication tool for the manufacturers. From a general process point of view:: - In view of a smooth process and according to the manual, we could expect that all HTA-related participants are active at that stage of the process implying there should not be any TBD in the list of participants. Involving participants in the middle of the process could jeopardize the quality of the whole work. - Stakeholders' involvement: we welcomed the possibility to have a face-to-face meeting. We see this step as an added value to the process allowing clarifying questions and engaging in a dialogue. We appreciated the flexibility with regards to the number of participants from the manufacturer side and the openness to bring clinical experts to the table providing their experience and views on the disease management, the guidelines, the current practices and the therapy. - We would consider as a great improvement to the REA process the inclusion from the beginning of the process of other stakeholders like the relevant physician society and the patients. They can comment for example on the patient selection, current	See answers above.

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				practices and guidelines. Patients would bring a unique type of information that would help completing the traditional quality of life and functional outcome measures. For instance, being able to perform usual activities such as walking 300 meters to go to the grocery store and coming back without help means a lot in terms of independence, absence of need of daily medical support etc and that is not fully captured by validated patient outcome tools. - The scoping meeting should be organized before the file submission by the manufacturers in order to align the content with the PICO profile and the expected evidence.	