Public consultation on "Duodenal-jejunal bypass sleeve (Endobarrier®) for the treatment of obesity"
Compilation of comments

Public consultation: List with comments and responses on the first draft Project Plan produced within WP5 Strand B on "Duodenal-jejunal bypass sleeve (Endobarrier®) "

The draft Project Plan on "Duodenal-jejunal bypass sleeve (Endobarrier®) for the treatment of obesity" was open to public consultation between 21 March and 4 April 2013.

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

1. European Diagnostic Manufacturers Association, Address: Place des Maieurs, 2; 1150 Brussels – Belgium, Telephone: +32 (2)777 02 78; + 49 173 3480476

Page of the draft Project plan	Comments #	Comment	Authors' reply
5	1.	The intervention is a device: Why should the HTA Core Model for pharmaceuticals be applied? Given that this model has only been published very recently, it is for time reasons impossible to comment on the appropriateness of this model for the question posed in this pilot.	The assessment is intended as a pilot project to test and adapt the HTA Core Model for rapid relative effectiveness model of pharmaceuticals to other technologies.
6	2.	"evidence-based clinical guidelines": citations could be given	Citations for guidelines have been included.
6	3.	Surrogate markers: Methods papers from Joint Action 1 were mentioned to be available on April 1st 2013, but are not publicly available. Validity of the this use of surrogate makers can only be assessed in knowledge of final JA1 paper on surrogate markers and informed by appropriate medical guidance.	The documents are publicly available at https://5026.fedimbo.belgium.be/outputs/methodological-guideline-rea-pharmaceuticals-surrogate-endpoints.
7	4.	Please define all abbreviations	Abbreviations/acronyms have been defined.
7	5.	There is no reason to exclude observational evidence for clinical effectiveness. It can also be quality assessed and can give valuable insight into health topics. For learning health care systems it is essential to include observational evidence.	We agree and this is the reason why we include 'prospective controlled studies' (in contrast to 'randomised controlled trials') for the evaluation of clinical effectiveness. Nowhere in the project plan do we state that observational studies are excluded to assess clinical effectiveness (except if they are uncontrolled).
7	6.	Using the GRADE methodology should at least be justified.	Justification on using the GRADE methodology has been included: "Efficacy and safety will be assessed by using the GRADE-methodology as this methodology allows for a transparent summary of the evidence in a qualitative manner."