EUnetHTA JA2 WP5 –STRAND B
Public Consultation comments and authors' replies on the Draft Project Plan on Biodegradable stents for benign refractory esophageal stenosis

The Draft Project Plan on Biodegradable stents for benign refractory esophageal stenosis was open to public consultation between 12 May and 2 June 2014.

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:

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ELLA-CS	Andrea.Mistrikova@ellacs.eu

Summarized comments and replies:

Comment #	Page	Line number	Comment received from	Comment	Author's reply
1.	6	Table 3 Intervention	ELLA-CS	"The stent is made of polydioxanone, Which is a polymer degradable by hydrolysis, and mainly excreted in urine, the remainder being Eliminated by digestive or exhaled as CO2." It is inaccurate because it is not polydixoanone excreted but its degradation products such as oxalic acid (Czech oxalic acid), which is excreted in the urine and serine, which is metabolized to pyruvate (in Czech language pyruvic acid) which is in the citrate cycle and finally converted to CO2 and water. The degradation to the oxalic acid is not the main issue, but minor degradation pathway. More is metabolized to serine and much more leave feces as fragments of fibers. Here is a table: Figure No. 1: Schematic illustrating the in vivo degradation of resorbable polymers (Hollinger JO and Battistone GC: Biodegradable bone repair materials. Synthetic polymers and ceramics. Clin Orthop 207: 290, 1986).	Agree. We have changed the project plan in order to eliminate inaccurate statements

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				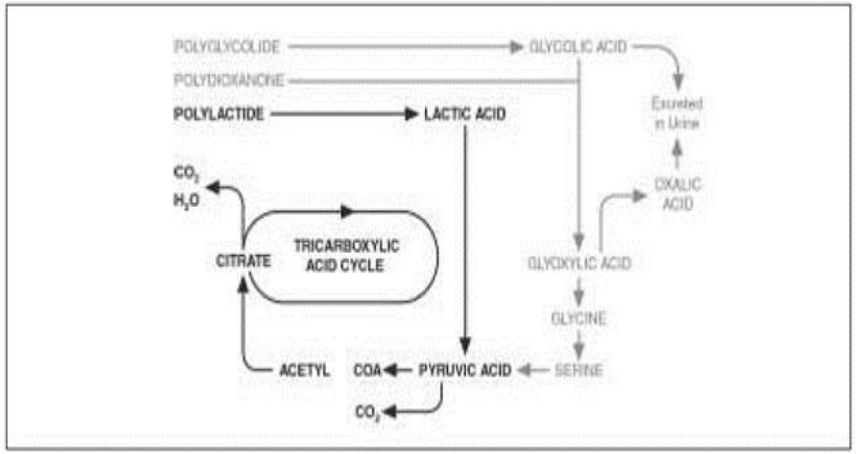	
2.	6	Table 3/Comparison	ELLA-CS	„Self-Expanding Metal Stents are not considered as comparator because they are not used for benign stenosis." This is only partly true, because SEMS are quite often used in benign stenoses "off label". These restrictions apply to a large extent for the USA, where the FDA has authorized for use in benign esophageal lesions only 3 SEMS covered, retrievable-see: (Sharma P. et al. Role of Esophageal Stents in Benign and Malignant Disease. Am J Gastroenterol 2010; 105:258–273): FDA-approved fully covered SEMSs include the Niti-S (TaeWoong) and the covered Wallflex (Boston Scientific, Natick, MA) The Niti-S prosthesis has been available in Asia and Europe for several years. Recently, the Alveolus esophageal stent system was introduced and is approved by the FDA for maintaining esophageal lumen patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and for occlusion of esophageal fistulas.	We agree to delete the sentence considering that is not completely clear that SEMS could not be used for benign stenosis.

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				Please see also the link on the degradation of polydioxanone: ASM Medical Material Database *The degradation product of the in vivo degradation of poly(dioxanone) is glyoxylate, which is excreted in the urine or converted into glycine, which can then be broken down into carbon dioxide and water by the citric acid cycle (Maurus and Kaeding 2004).*	