

**EUnetHTA JA3 WP4 - other technologies,  
OTCA23 Biodegradable rectum spacers to reduce toxicity for prostate cancer**



Project Plan Comments from Clinical Experts and Feedback Author Team

<b>Comment from</b> <i>Insert your name and organisation</i>	<b>Page number</b> <i>Insert 'general' if your comment relates to the whole document</i>	<b>Line/ section number</b>	<b>Comment and suggestion for rewording</b> <i>Please insert each new comment in a new row.</i>	<b>Character of comment</b> <ul style="list-style-type: none"> <li>• 'major'<sup>a</sup>=1</li> <li>• 'minor'<sup>b</sup>= 2</li> <li>• 'linguistic'<sup>c</sup> =3</li> </ul> <i>Please indicate your choice by writing the according number in this field, e.g. for major choose "1".</i>	<b>Author's reply</b>
TT	Pg 9		@clinical experts: is there a criteria that defines acute and late toxicity. Examples I found in the literature are NCI-CTC criteria or now called CTCAE v 5.0 (2017)  CTCAE should be used		CTCAE adopted as per suggestion
TT	Pg 10		@clinical experts, what staging system is preferable, I found TNM staging system or stage 0 to IV or the 2010 reference to RTOG and LENT as stated  TNM		TNM plus reference added as per suggestion
TT	Pg 13		@clinical experts, do we include all types in the assessment of only adenocarcinoma  All should be adenocarcinomas, although small portions of other differentiating should be allowed		The text will indicate we will include individuals with adenocarcinoma or other type of prostate cancer if receiving radiotherapy for curative purposes. Differences in radiotherapy among types of prostate cancer will be noted.
TT	Pg13		@clinical experts, is this correct? Meaning patients receiving palliative care are out of the Population  No chemo		Chemotherapy taken out - hormone therapy will remain.
TT	Pg14		@ clinical experts: is this an appropriate comparator if we find studies comparing one spacer to another?		Head to head comparator removed, only management pathway without the technology (e.g. hormone therapy and/or radiotherapy) remained as a

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			No, we will not find this in any study of high enough quality		comparator
TT	Pg14		PSA as an outcome? PSA is not relevant		We will include PSA as an outcome as this information may be important depending on the context
JT	Pg14		PSA as an outcome? Biochemical relapse in a classical and relevant endpoint in prostate cancer		We will include PSA as an outcome as this information may be important depending on the context
JT	Pg 12		@clinical experts do we include all types in the assessment or only adenocarcinomas  These other types are only a minority and may not always require RT, I would recommend adenocarcinomas		The text will indicate we will include individuals with adenocarcinoma or other type of prostate cancer if receiving RT for curative purposes. Differences in radiotherapy among types of prostate cancer will be noted.
JT	Pg13		May be necessary to specify whether there should be a limit in terms of prostate volume in addition to stage and if N+ patients would also be included		Addressed in row above
JT	Pg13		And to specify if postoperative patients are excluded		Added under population/exclusion criteria
JT	Pg12		@clinical experts, is this correct? Meaning patients receiving palliative care are out of the "population"  Yes, it sounds relevant as palliative schemes man not lead to dose schemes similarly toxic to the rectum		Added as an exclusion criteria under population
JT	Pg 13		Intervention: There is should be said how, with which tools, under which type of anesthesia, duration of procedures, need for short stay at hospital, need for painkillers, complications, etc.		The TEC and CUR chapters will provide general information about this  Although these are important

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			Insertion said temporary appears in contradiction with spontaneous resorption of product, needs clarification/editing process for control of procedure should be specified		outcomes, the aim was to have a limited set of the most important outcomes
JT	Pg 13		Human collagen: quantity injected and justification should be specified		Human collagen removed from interventions included as no EU company found
JT	Pg 14		"state of the art radiotherapy" - details here do not appear to be consistent with paragraph above as the former also includes brachytherapy It is fine to include brachytherapy Other techniques like proto therapy although little used at the moment for prostate cancer might be worth adding		Paragraph content modified to include suggestions and flow of information. Proto therapy included as per suggestion.