July 2020

PROCEDURE MANUAL
PHARMACEUTICAL JOINT ASSESSMENTS
MANUFACTURERS

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List of abbreviations

CET	Central European Time
CHMP	Committee for Medicinal Products for Human Use
COI	Conflict of Interest
COIC	Conflict of Interest Committee
CA	Confidentiality Agreement
DOI	Declaration of Interest
DOICU	Declaration of Interest and Confidentiality Undertaking. *Note: now split in to COI and CA.*
DR	Dedicated reviewer
EC	European Commission
EoI	Extension of Indication
F2F	Face-to-face
HTA	Health Technology Assessment
JA3	EUnetHTA Joint Action 3
JA	Joint Assessment
LoI	Letter of Intent
LoMI	List of Missing Items
LoR	List of Requirements (result of scoping F2F meeting)
LoSQ	List of Scoping Questions (preparation scoping F2F meeting)
MAA	Marketing Authorisation Application
(p)MAH	(prospective) Marketing authorisation holder
PC	Patient & Consumer
PICO	Population/Intervention/Comparator/Outcomes
PM	Project manager EUnetHTA WP4 CoLP
PTJAXX	Project Identifier: Pharmaceutical Joint Assessment XX
WP	Work Package

1 Objective of this Procedure Manual

This procedure manual is targeted at (prospective) Marketing Authorisation Holders ((p)MAH) who have submitted a compound for a Pharmaceutical Joint Assessment (PTJA) within Joint Action 3. It was compiled by Zorginstituut Nederland (ZIN), the Co-Lead Partner in EUnetHTA JA3 WP4 responsible for coordinating the Pharmaceutical Joint Assessments.

This procedure manual is used as the basis for each Pharmaceutical Joint Assessment. In section 2, project specific details, such as the composition of the Assessment team and important milestones will be documented. Section 3 explains each step of the procedure. In Table 2, the current procedures, tools and templates that are the basis for this assessment are listed. When a procedure, tool and/or template is under development/revision, this is indicated. Although not obligatory, the (p)MAH is advised to follow new/updated procedures, tools and/or templates.

Version History

Version	Date	Comment
V0.0	July 2020	Generic version of the procedure manual *This version is subject to (procedural) changes, therefore this version should not be used as the final version by (p)MAHs interested in submitting a compound for a Joint Assessment. Only after submitting a Letter of Intent, the (p)MAH will receive the procedure manual valid for the respective assessment.*
V1.0	Date	Procedure manual updated with project specifics
		[e.g. adopted change procedure in..]

2 Project Specific details

Project Identifier	PTJA[XX]
Short Title	[Compound] for the treatment of [indication]
Prospective MAH	
Company Name	[Company Name]
Primary contact person	[Name] e-mail: telephone:
If applicable: Secondary contact person	[Name] e-mail: telephone:
Project Management	
Primary contact person	[Name] e-mail: telephone:
Secondary contact person	[Name] e-mail: telephone:
General	WP4 CoLP Pharmaceuticals e-mail: WP4_Pharmaceuticals@zinl.nl

3 Procedure, Tools & Templates Checklist

This section lists the procedures, tools & templates that have to be followed during PTJAXX. An overview of the timelines can be found in Section 4.

Please note that throughout this manual any referral to Project Manager (PM) is to the EUnetHTA Project Management team. The PM centrally coordinate the Joint Assessment project and is the contact person for the (p)MAH and the Assessment Team. All questions and communication related to the EUnetHTA Joint Assessment should be send to/will be shared by the PM. For questions related to national uptake of the EUnetHTA report, the (p)MAH should follow normal national procedures.

[To be added: project specifc info, e.g. on regulatory procedure if relevant]

3.1 Start-up Phase

The Joint Assessment process starts as soon as the Letter of Intent (LoI) is received, around day 0 of EMA submission. The version that is valid for this assessment can be found in Table 2. To establish an Assessment Team, the PM sends out a redacted LoI to all EUnetHTA WP4 pharma partners in a call for collaboration. The following LoI elements will be redacted for the call for collaboration:

- Market authorisation status (section 5) except for the expected date of CHMP opinion, which is needed for planning purposes
- Contact details (section 15 and 16)

In addition, the PM will share this procedure manual to inform the (p)MAH about the procedures, tools & templates that are valid for the current assessment. All relevant documents will also be shared with the (p)MAH via e-mail. For further information about the template and the submission, please see Table 2.

There is no need to submit a hard copy of the LoI. The LoI can be send to WP4_Pharmaceuticals@zinl.nl and should be addressed to 'WP4 CoLP Pharmaceuticals'.

The (p)MAH can decide who signs the LoI. Please note that it is important that the person who signs the LoI can take responsibility, as the LoI marks the official kick-off of our Joint Assessment process.

3.1.1 Selection of the Assessment Team

EUnetHTA follows a set of selection criteria when establishing the Assessment Team. Please visit our website for more details on the selection criteria. EUnetHTA cannot give details about the which organisations expressed interest in being part of the Assessment Team. EUnetHTA will only establish the Assessment Team ~6 months prior to CHMP opinion. Once the team is selected, each individual assessor and reviewer has to pass a Conflict of Interest examination (please see section 3.1.2). This can take up to 4 weeks. Therefore, EUnetHTA can only share the organisations that are part of the Assesssment team ~4 months prior to CHMP opinion.

EUnetHTA will assign members to the following Assessment Team roles:

- 1 Author organisation:
  - Leading role in both the scoping and assessment.
  - Responsible for the content-related process.
  - Ultimate responsibility for quality assurance.
- 1-2 Co-author organisations:
  - Support the author in all project phases.
  - Depending on the collaboration mode, responsible for preparing sections independently.
- 2-4 Dedicated Reviewer organisations:
  - Responsible for quality assurance by thorough review of the project plan and draft assessment.
  - Review of methods, results and conclusions based on the original studies included.
- OPTIONAL: Observer:
  - This role is specifically designed for partners new to EUnetHTA or who want to learn

more about the Joint Assessment production process. Observers will not have an active role, but will have access to all the data.

In addition, the team assigns an information specialists and statistical specialist for the Joint Assessment.

Authoring Team and Assessment Team
Within EUnetHTA two terms are commonly used to indicate (a part of) the team, namely the 'Authoring Team', consisting of the author and co-author and the 'Assessment Team', including the Authoring Team, Dedicated Reviewers and (if applicable) observers.

3.1.2 Conflict of Interest and EUnetHTA Confidentiality Agreement
All participating individuals from the Assessment Team, the PM, Medical Editor (ME), individual patients and healthcare professionals will have to sign our Declaration of Interest (DOI) and Confidentiality Agreement (ECA) forms (previously called DOICU form). Please find here further details on EUnetHTA's Conflict of Interest (COI) and ECA procedures.

Due to EUnetHTA's strict COI policy, EUnetHTA cannot accept individual patients or healthcare professionals that are recommended by the (p)MAH.

3.1.3 Announcement of Assessment Start
Once the Assessment Team is established and their COI is assessed, the (p)MAH will be informed about the participating organisations. Within one week after this communication, the start of the Joint Assessment will be announced on the EUnetHTA website (REA table) and on EUnetHTA social media.

- REA table: "[compound] indicated for the treatment of [population]"
- Social Media: "EUnetHTA is pleased to announce the start of the next Pharmaceutical Joint Assessment. PTJAXX addresses '[compound] for the treatment of [population]', submitted by @(p)MAH. We are delighted that @AUTHOR and @CO-AUTHOR are authoring this assessment. We will be issuing an Open Call for Patient Input in due course."

The PM will reach out to the (p)MAH to confirm the title to be used in the REA table and the text used in the social media message. In addition, the (p)MAH and the Authoring Team will be given the option to opt out of being tagged in the social media messages.

3.2 Scoping Phase

3.2.1 Project Plan
In the scoping phase, the Authoring Team develops the Project Plan, which includes the PICO (section 3.2.2) and general methods to be applied in the assessment. The first draft of the Project Plan will be reviewed by the Dedicated Reviewers. The second draft of the Project Plan incorporates the Dedicated Reviewers' feedback and is shared with the (p)MAH as preparation for the scoping F2F meeting (section 3.2.5). Please note that the Project Plan is not shared for review by the (p)MAH. The Project Plan can be further updated by the Authoring Team based on the discussions during the scoping F2F meeting, patient input (section 3.2.3) and the final CHMP opinion. The final Project Plan is published on the EUnetHTA website once CHMP opinion is adopted.

3.2.2 PICO Survey
EUnetHTA aims to adopt (a) PICO question(s) applicable for most European countries and therefore develops product specific PICO surveys. The Authoring Team uses the PICO provided by the (p)MAH in the LoI as a basis to develop the PICO survey. The PICO used in the survey can thus be different from what the (p)MAH has suggested in their LoI. All WP4 partners are invited to indicate the relevance of the PICO(s) proposed by the Authoring Team via this survey.

The Authoring Team is responsible for the decision on the final PICO(s), but the aim is to include the scope of most of the partners. This could mean that the Authoring Team decides to e.g. include an off-label comparator in the PICO, if this is of relevance to the majority of respondents. Please note that EUnetHTA will not share the individual responses to the PICO survey with the (p)MAH or any other external stakeholder.

3.2.3 Stakeholder Engagement
EUnetHTA established a Task Group to develop recommendations for stakeholder engagement, focused on patient organisations and healthcare providers.

Open Call for Patient Input
The PM organises an open call for patient input as part of the standard patient engagement procedure. EUnetHTA uses a dedicated form to collect patient input for the assessments. This form is a modified version of the "Patient Group Submission Template for HTA of Health Interventions", which was developed by HTAi. Only patient organisations are expected to complete the survey and they are required to disclose information regarding their funding. Although the survey and other information is currently only available in English, submission in the national language of the Authoring Team is also allowed.

The open call for patient input is considered during the scoping phase of the assessment. The open call for patient input is generally online for 1-2 months and includes general questions on the disease and expectations of "a new therapy". Once the call is online, the PM will announce the call using several strategies:

- Email to relevant patient organisations identified and recommended by the EMA.
- Social media message to announce the open call.
- Share the open call for patient input with the HTA Network Stakeholder Pool.
- Ask the Assessment Team to disseminate the call in their national network.
- Reach out to the (p)MAH with the link of the open call and the request to share the link within their network. An introductory text will be included which can be used to distribute the open call.

It remains the responsibility of the Authoring Team to decide on how to include the results from the open call for patient input. If deemed relevant by the Authoring Team, the open call for patient input can be complemented with different patient engagement methods (e.g. interview). For further information, please see EUnetHTA's recommendations for patient engagement in REAs.

EUnetHTA cannot share any patient responses with the (p)MAH nor any early information on how the patient input will be used in the Joint Assessment report. However, the methods will be explained in the project plan and documented in the Assessment Report.

Healthcare Professionals
EUnetHTA aims to involve two healthcare professionals in both the scoping and the assessment phase. Similar as for patient organisations, the PM will reach out to EMA to request contact details of the healthcare professionals and/or medical societies they have worked with for the respective pharmaceutical compound. The level of involvement of a healthcare professional largely depends on the level of Conflict of Interest (COI) he/she has. For accepted healthcare professionals, a Question and Answer (Q&A) approach will form the basis for the engagement. This means that the Assessment Team could ask scoping questions in order to help define the PICO and/or critical outcomes. In addition, the Assessment Team can also ask the healthcare professionals questions in the assessment phase e.g. regarding patient characteristics, common practise and interpretation of efficacy and safety results. Interaction between the Assessment Team and the healthcare professional will take place via the PM.

The involved healthcare professional(s) will be named on individual or institutional basis in the project plan and the assessment report. In case the healthcare professional is involved in reviewing the Project Plan, the comments provided together with the response of the Authoring Team will be made publicaly available once the Project Plan is published. EUnetHTA will not inform the (p)MAH about the selected healthcare professional prior to publication of these documents.

EUnetHTA has developed recommendations and methods for the engagement of healthcare professionals in REAs in their Patient, Consumer and Health Care Professional Task Group which can be found here.

3.2.4 Scoping Document
The Template version of the Scoping Document that is valid for this assessment can be found in

Table 2. The Scoping Document should be used to explain the (p)MAH's perspective on the PICO (& justification of this), the methods/analysis used and the reasons for their use. When indirect comparisons are part of the (p)MAH's analysis, the procedure and considerations of such analyses need to be explained in the Scoping Document. The main goal of the Scoping Document is to better inform the Authoring Team for the scoping F2F meeting and thus should not be a draft Submission Dossier. Please note that the Scoping Document should not address any results from clinical trial(s) nor will the Authoring Team provide any assessment of appropriateness of the suggested methods.

Please limit the Scoping Document to a maximum of 10 pages. We advise the (p)MAH to add the LoI as an appendix to the Scoping Document, which allows referencing to some of the information already discussed in the LoI.

3.2.5 Scoping Meeting

The Scoping face-to-face (F2F) meeting is the only possibility for a direct interaction between the (p)MAH and the Authoring Team. Before and after this meeting, communication will take place via the PM and only if this is requested by the Authoring Team.

When	Ideally, the scoping F2F meeting is held: • ~3 months prior to CHMP opinion for an initial or type II MAA[1] • ~2 months prior to CHMP opinion for an accelerated MAA[2] The PM of the assessment will reach out to schedule the date.
Duration	~3 hours
Location	Office of Zorginstituut Nederland in Diemen, the Netherlands.
Attendees	Author, Co-Author, (p)MAH and Project Manager. The (p)MAH can bring a maximum of eight participants in person to the scoping F2F meeting. The (p)MAH is advised to bring a representative from regulatory affairs and the representatives of the national affiliates of the countries from the author and co-author. If the (p)MAH wishes to bring a patient and/or healthcare professional to the scoping F2F meeting, this person would be considered as an industry representative and thus their input will not be considered as patient or healthcare professional input. A TC-option can be arranged if required. No more than five attendees from (p)MAH can dial in. Participants on the phone can also participate in the discussion.
Agenda	12:30-15:30 scoping meeting - 12:30-12:40: Introduction round - 12:40-12:50: Welcome and introduction from ZIN - 12:50-13:10: Introduction Authoring Team – anticipated national use of Joint Assessment & PICO Joint Assessment - 13:10-13:30: Lunch provided by ZIN *(optional)* - 13:30-13:50: Presentation by (p)MAH - 13:50-15:15: Discussion on PICO and data/information requests - 15:15-15:30: Closing
Objective	Open dialogue around the PICO and data analyses. The Authoring Team can use the information provided in the scoping F2F meeting to update the draft Project Plan, however, the Authoring Team will decide on the final PICO for the assessment. The final PICO will also be based on the CHMP opinion and will therefore be included in the final Project Plan. Please note that the objective is not to reach final decisions during the meeting itself.
Preparation - List of Scoping Questions (LoSQ) and draft Project Plan (PP)	The PM will share the draft Project Plan, including the PICO, and the List of Scoping Questions (LoSQ) with the (p)MAH approximately one week in advance of the scoping F2F meeting. The (p)MAH is advised to incorporate responses to the LoSQ within their presentation where possible. The next agenda item allows (further) discussion on the LoSQ.
Outcome - List of Requirements (LoR)	No official minutes will be taken, nor will the meeting be recorded. The Authoring Team prepares a List of Requirements (LoR) that the (p)MAH should consider when preparing the Submission Dossier, either to update the Submission Dossier accordingly, or explain why certain elements are not/cannot be provided. The LoR will be shared approximately one to two weeks after the scoping F2F meeting. Should relevant updates be made to the PP after the scoping F2F meeting, the revised PP will be shared with the (p)MAH.

[1] Initial marketing authorization applications (MAA) being assessed under standard timelines or type II variations (addition of a new therapeutic indication)
[2] Initial MAAs being assessed under accelerated timelines

3.2.6 Submission Requirements & Citation/Publication Policy
EUnetHTA published their submission requirements. This document outlines EUnetHTA's publication and citation policy and clarifies General Data Protection Regulation (GDPR) compliance. The submission requirements document also includes an overview of the publication policy per EUnetHTA product. Please see Table 2 for the version valid for this assessment.

3.2.7 Submission Timelines
For initial marketing authorisation applications (MAA) EUnetHTA requests the Submission Dossier one month in advance of expected CHMP opinion. For accelerated procedures, Type II variations (Extension of Indication) or when the process overlaps with summer/Christmas break, EUnetHTA requests the Submission Dossier at least six weeks prior to CHMP opinion in order to meet the (shorter) regulatory timelines of the EMA.

3.2.8 Submission Dossier Template
The Submission Dossier Template version that is valid for this assessment can be found in Table 2.

The (p)MAH is obligated to follow the template, including the order of the sections and sub-sections. The (p)MAH is invited to add an executive summary. In addition, tables can be added or, in existing tables, the (p)MAH can change the layout to improve data presentation. However, all requested content needs to be completed. Incompleteness of the Submission Dossier can be mentioned (and discussed) by the Authoring Team in the assessment report. Please note that an incomplete Submission Dossier might negatively influence national uptake of the EUnetHTA report. Once the Submission Dossier is submitted, the (p)MAH is not allowed to provide any additional or supporting information, unless requested by the Authoring Team.

3.2.9 Check for Formal Completeness
Once the Submission Dossier and attachments are received, the Authoring Team has 10 calendar days to check the completeness of the dossier. A list of missing items (LoMI) will be shared with the (p)MAH by the end of this check. The (p)MAH then has 5 calendar days to provide the missing items/response to the requests via an amended Submission Dossier.

The objective of the formal check of completeness is to limit the interaction (via PM) between the (p)MAH and the Authoring Team during the actual assessment. However, if deemed necessary, the Authoring Team may request further clarification during the assessment. Depending on the type of request, a deadline (with a maximum of 5 calendar days) to provide the requested information will be communicated.

3.2.10 Grace Period
Although EUnetHTA does not have clock-stops, a Grace Period to amend the Submission Dossier is allowed if CHMP opinion differs from what was anticipated and only to those sections impacted by the CHMP opinion. The need and duration of a Grace Period has to be approved between the Authoring Team, PM and (p)MAH and can take a maximum of 10 calendar days (starting once CHMP opinion is available).

During the Grace Period the Authoring Team will update the Project Plan, which will be publicated approximately 1 week after CHMP opinion.

3.2.11 Methodological Guidelines
Please see an overview of all Methodological Guidelines that are applicable for the Joint Assessment in Table 2.

3.3 Assessment Phase
For the assessment report, the ultimate responsibility lies with the Author. In case of major disagreements within the Assessment Team, the PM will mediate the discussion.

3.3.1 Factual Accuracy Check
Each Authoring Team decides whether they want to include a factual accuracy check in their assessment. Such checks in the process have been established as good practice.

The factual accuracy check takes place in parallel with the medical editing (see section below) of the draft assessment report and takes 5 calendar days. Comments submitted after the deadline or in a different format will not be considered. The (p)MAH can only comment on fact-related typos/mistakes (e.g. numbers). Please follow the guidance/checklist as presented in Table 2.

Only comments within the scope of a factual accuracy check will be considered and answered by the Authoring Team. Comments that, according to EUnetHTA, do not belong to a factual accuracy check, will not be considered nor answered by the Authoring Team. The comments made by the (p)MAH and the answers of the Authoring Team to the comments will be published on the EUnetTHA website at the same time EUnetHTA publishes the final Joint Assessment report.

3.3.2 Medical Editing
EUnetHTA involves a medical editor to check the second draft of the assessment report in case medical editing (e.g. English language) cannot be performed by the Authoring Team. The medical editor focusses on the main body of the text and reviews the text for sense and clarity, internal consistency of terminology, layout and for grammar and spelling. Comments and suggestions by the medical editor will be reviewed by the Authoring Team before they will (or not) be incorporated.

3.4 Publication & Evaluation
3.4.1 Announcement of Publication
EUnetHTA aims to publish the Joint Assessment report 2-3 weeks after the expected EPAR publication date. The latest version of the Core Submission Dossier (e.g. amended dossier) will be published together with the Joint Assessment report as per submission requirements (section 3.2.6).

The final publication date will be communicated in the final Project Plan, which will be published after CHMP opinion. Approximately one hour prior to publicaition of the Joint Assessment report, the PM will inform the MAH about this and will share – for infomratin only – the Joint Assesssment with the MAH. The version of the attached report will be the final version. However, minor last minute editing updates might occur.

The publication of the Joint Assessment report on our website will be announced via email to the Assessment Team, healthcare professionals (if included), the MAH, and to our EUnetHTA partners. In addition, the publication of the Joint Assessment report will be announced via LinkedIn, and Twitter.

3.4.2 Evaluation – Survey for MAH
After publication of the Joint Assessment report, the PM will share a feedback questionnaire with the MAH (word format). The MAH is asked to complete the questionnaire within one month and is asked to share one consolidated response on behalf of the organisation.

3.4.3 Error Reporting Procedure
In case the MAH identifies a factual error in the published Joint Assessment report, EUnetHTA will start a so-called error reporting procedure. By means of this procedure, EUnetHTA will assess the (impact) of the error and decides whether the report needs to be updated.

4 Joint Assessments - Timelines

The project timeline is closely related to the EMA market access procedure. As the EMA procedure is not fixed, the project timelines could change until CHMP opinion is adopted. It is therefore important for EUnetHTA to always work with the 'best case' scenario, i.e. assuming the fastest feasible EMA track for the applicant's intervention. However, the (p)MAH should keep the PM updated as soon as any changes in EMA regulatory timelines are expected.

Table 1: Indicative timeline for Pharmaceutical Joint Assessment

Milestone	Responsible	Timeline per application type*		
		Standard Initial MAA	Type II variation (EoI)	Accelerated Initial MAA
Letter of Intent (LoI)	(p)MAH	Day 0 of EMA submission		
Assessment team (institutional level only)	PM	~4 months before CHMP opinion		
Publication of assessment start in REA table and on Social Media	PM	1 week after communication of Assessment Team to (p)MAH		
Receipt of Scoping Document	(p)MAH	2 month prior to scoping F2F meeting		
List of Scoping Questions (LoSQ)	AT+PM	1 week prior to scoping F2F meeting		
Scoping F2F meeting	PM+AT+(p)MAH	3 months prior to CHMP opinion	3 months prior to CHMP opinion	2 months prior to CHMP opinion
List of Requirements (LoR)	AT+PM	1 week after scoping F2F meeting		3-5 days after scoping F2F meeting
Receipt of Submission Dossier + Attachments	(p)MAH	1 month prior to CHMP opinion	1.5 months prior to CHMP opinion	
Check for formal completeness of the Submission Dossier	AT	10 calendar days after receipt Submission Dossier		
Provide missing items/comment on requests from check of formal completeness	(p)MAH	Within 5 calendar days after receipt List of Missing Items (LoMI)		
CHMP opinion	EMA	Day 0 of assessment phase		
OPTIONAL: Grace Period	PM+(p)MAH	Only if CHMP opinion differs from what was anticipated and maximally 10 calendar days. Need and duration of a Grace Period has to be approved between the AT, PM, and (p)MAH		
Start of Assessment	AT	Once CHMP opinion is given		
Publication of project plan	PM+AT	Within 1 week after CHMP opinion (or Grace Period, if applicable) Publication date of final Joint Assessment report and Submission Dossier updated in REA table		
Medical editing/factual accuracy check	ME + (p)MAH	~2-3 weeks prior to publication		
EPAR	EMA	81 days after CHMP	70 days after CHMP	70 days after CHMP
Publication final Joint Assessment report and Core Submission Dossier	PM+AT	~2-3 weeks after publication of EPAR		

*Please note that project specific timelines might deviate from the indicated timeline.

5 Appendix – Table of Tools, Templates, and Procedures

Table 2 – overview of tools, templates and procedures

Tools/ template/ procedure		Version	Status
Letter of Intent	The version is called "EUnetHTA_Letter-of-Intent_Template_v2.0-1.docx" and can be accessed here.	2.0; 2020	
Scoping document	The version is called "EUnetHTA_Scoping-Document-Template_v2.0.docx"	2.0; 2020	
Submission Requirements	The submission requirements – pharmaceuticals can be accessed here.	2.0; 2019	
Submission Dossier Template	The version is called: "JA3-WP4-Pharma-Core-Submission-Dossier-for-MAH-Shortv2.0.docx" and can be accessed here.	2.0; 2020	
Factual Accuracy Check guidance	To be shared via e-mail at time of the fact check phase. Can be accessed here.	1.0, 2018	
Methodological Guidelines	Process of information retrieval for systematic reviews and health technology assessments on clinical effectiveness	2.0, 2019	
	Endpoints used for Relative Effectiveness Assessment: Clinical Endpoints	2.0; 2015	
	Endpoints used for Relative Effectiveness Assessment: Composite Endpoints	2.0; 2015	
	Endpoints used in Relative Effectiveness Assessment: Surrogate Endpoints	2.0; 2015	
	Endpoints used in Relative Effectiveness Assessment: Safety	2.0; 2015	
	Endpoints used for Relative Effectiveness Assessment: Health related quality of life and utility measures	2.0; 2015	
	Comparators & Comparisons: Criteria for the choice of the most appropriate comparator(s)	2.0; 2015	
	Comparators & Comparisons: Direct and indirect comparisons	2.0; 2015	Update expected on the indirect comparisons part; to reflect reporting of ITC and NMA
	Levels of Evidence - Applicability of evidence for the context of a relative effectiveness assessment	2.0; 2015	
	Internal validity of randomised controlled trials	2.0; 2015	
	Internal validity of non-randomised studies (NRS) on interventions	1.0; 2015	
	Meta-analysis of diagnostic test accuracy studies	1.0; 2014	
	Therapeutic medical devices	1.0; 2015	
	Personalised Medicine and Co-Dependent Technologies	0.1; 2015	
	Methods for health economic evaluations - A guideline based on current practices in Europe	1.0; 2015	
	Practical considerations when critically assessing economic evaluations. Guidance document	1.0; 2020	
	Critical assessment of economic evaluations	-	Under development planned publication: 2020