

WP5 – Strand B

Rapid Assessments of other health technologies

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Outputs

- 6 joint pilot rapid assessments by Dec 2015
- 5 national/local reports published so far
- Update of HTA Core Model for Rapid Relative Effectiveness (ongoing)
- Piloting of submission file for medical devices in 2 joint assessments
- In 2 pilot assessments f2f scoping meetings held:
 - 5th pilot: 2 meetings with 7 representatives from 2 companies and 5 EUnetHTA members
 - 6th pilot: 2 meetings with 8 representatives from 4 companies and 6 EUnetHTA members



Strand B Assessments

	Duodenal-jejunal bypass sleeve for the treatment of obesity with or without type II Diabetes mellitus	Renal denervation for treatment resistant hypertension	Balloon Eustachian Tuboplasty for the treatment of Eustachian tube dysfunction
Duration	January 2013 – August 2013	April 2013 – December 2013	April 2014 – February 2015
Status	Published	Published	Published
Pilot team agencies, n	8	8	5
(Co-)Authoring HTA bodies	LBI-HTA (Austria) AAZ (Croatia)	NOKC (Norway) Avalia-t (Spain) CFK (Denmark)	FinOHTA/THL (Finland) HIQA (Ireland)
Dedicated reviewing HTA bodies	GYMEZSI (Hungary) HIQA (Ireland) HVB (Austria) ISCIII (Spain) NOKC (Norway) Charles University Prague (Czech Republic)	HIS (UK) FinOHTA/THL (Finland) AHTAPol (Poland) GYMEZSI (Hungary) IQWiG (Germany)	GYMEZSI (Hungary) HVB (Austria) AHTAPol (Poland)

Strand B Assessments

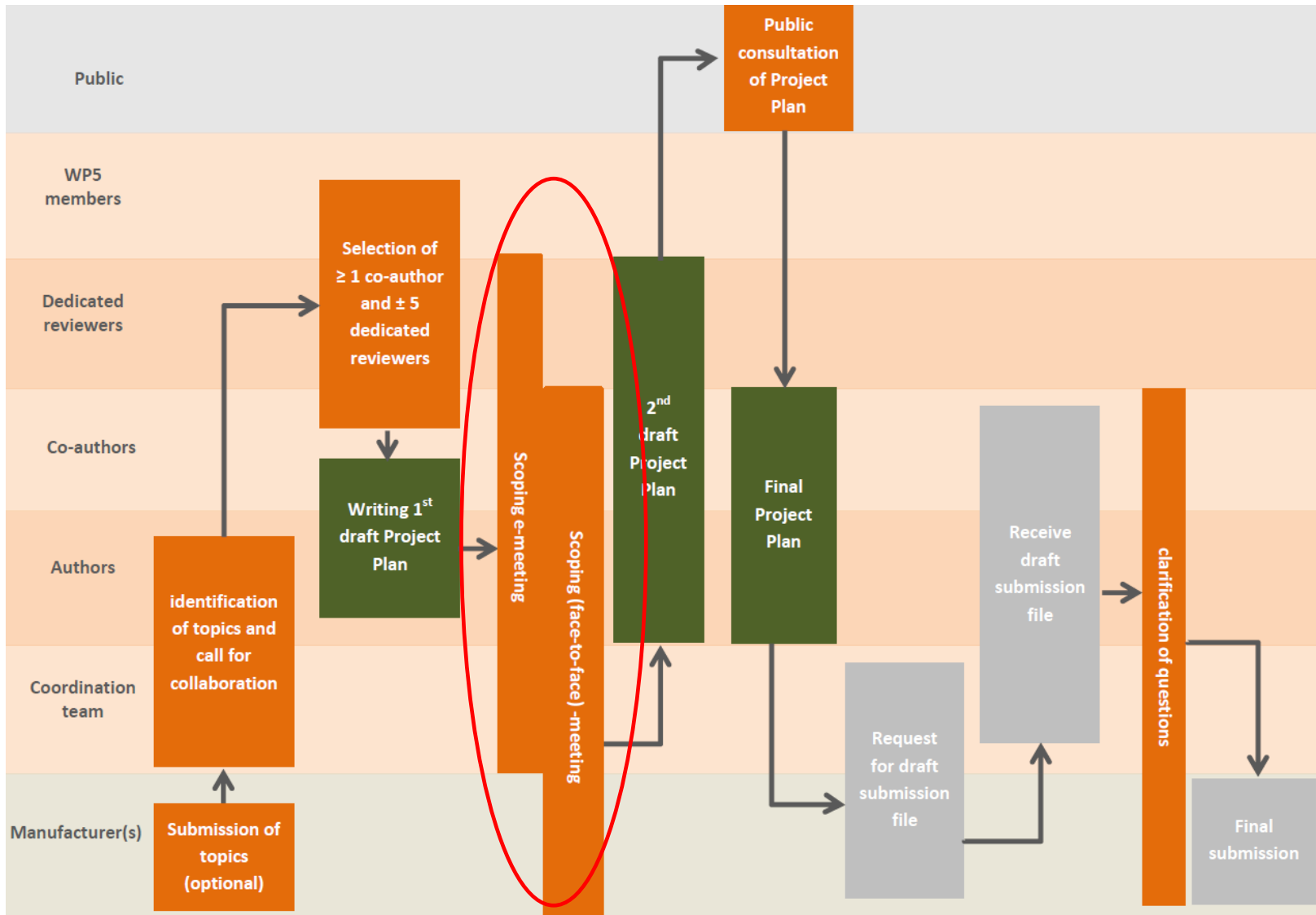
	Biodegradable stents for benign refractory esophageal stenosis	Transcatheter mitral valve repair in adults with chronic mitral valve regurgitation	Endovascular therapy using mechanical thrombectomy devices for acute ischaemic stroke
Duration	April 2014 – May 2015	November 2014 –October 2015	March 2015 – December 2015
Status	Published	Published	Ongoing (external review)
Pilot team agencies, n	5	8	7
(Co-)Authoring HTA bodies	ISCIII (Spain) SAGEM (Turkey)	Agenas (Italy) AAZ (Croatia) MoH (Slovak Republic)	HIQA (Ireland) IZPH (Germany)
Dedicated reviewing HTA bodies	VASPVT (Lithuania) Slovak Ministry of Health (Slovakia) LBI-HTA (Austria)	HAS (France) GÖG (Austria) AETSA (Spain) AAZ (Croatia) HIQA (Ireland) HIS (Scotland)	LBI HTA (Austria) CFK (Denmark) HAS (France) A.Gemelli Hospital (Italy) HIS (Scotland)

National Adaptation - Strand B Assessments

Joint Pilot Assessment	National reports	Directly used for decision-making
Duodenal-jejunal bypass sleeve for the treatment of obesity with or without type II Diabetes mellitus	LBI-HTA (Austria, July 2013) ZIN (Netherlands, July 2015) ISCIII (Spain, September 2014)	Austria Slovakia
Renal denervation for treatment resistant hypertension	-	2x Spain Austria Slovakia Norway
Balloon Eustachian Tuboplasty for the treatment of Eustachian tube dysfunction	AETSA (Spain, 2015)	Austria Slovakia
Biodegradable stents for benign refractory esophageal stenosis	LBI-HTA (Austria, August 2015)	Austria Slovakia

+ several assessments ongoing

Current processes: Scoping phase



Current processes: Topic selection & team building

Topic selection:

1. Call for collaboration:

- authoring agency selects 2 relevant topics and provides a rationale why they have been chosen (basic requirement: CE mark)
- members are asked to indicate which one is more relevant

2. **POP database:** overlaps in topics listed at POP

Pilot team:

- first author: from 1 organisation or institution
- co-author(s): from ≥ 1 co-authoring organisation or institution
- dedicated reviewers: 2 – 5 reviewing organisations or institutions
- at least 2 external experts
- coordination team



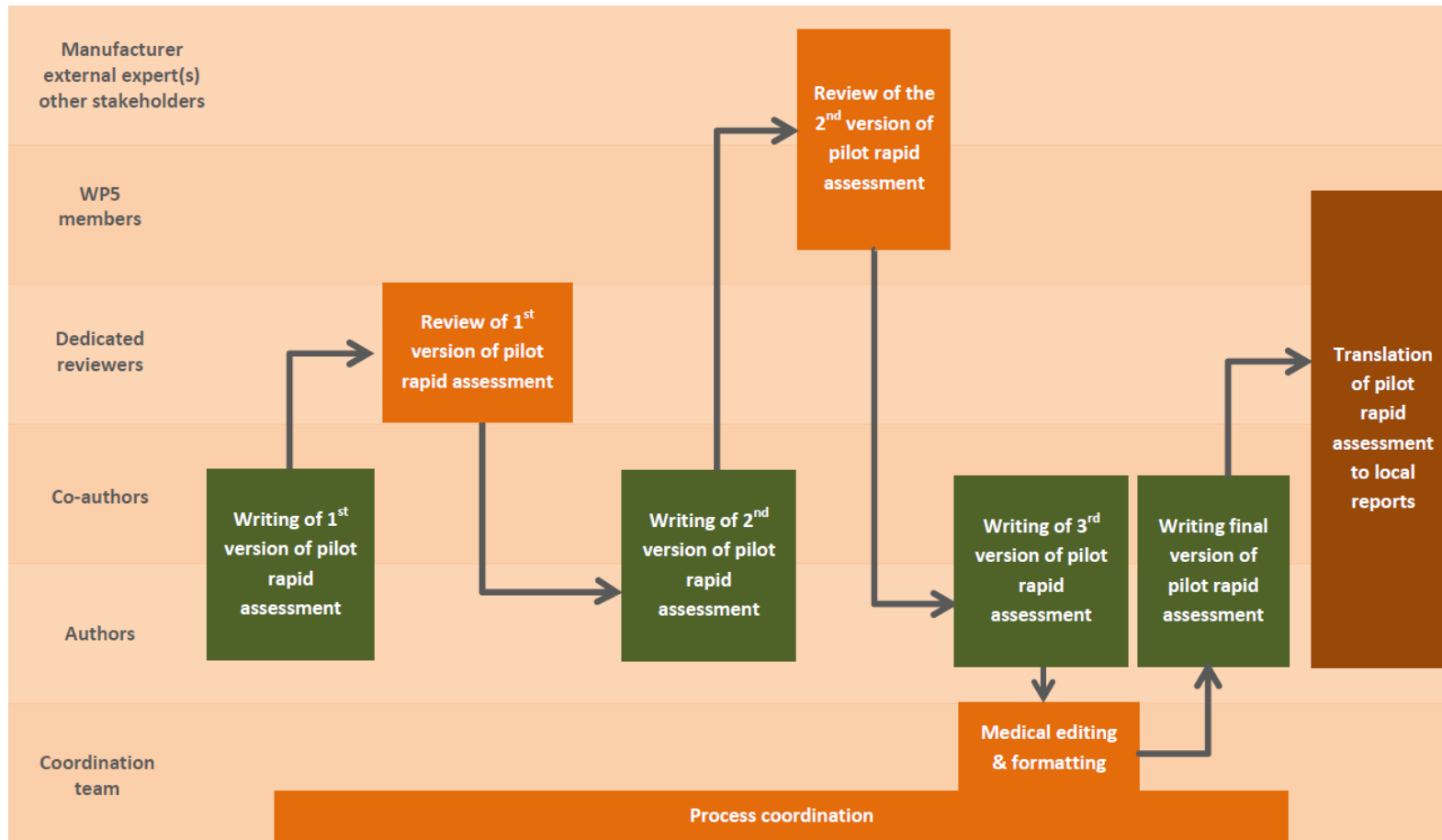
Current processes: Scoping phase

Consultation of draft project plan:

- Development of first draft by pilot team
- Scoping meeting with manufacturers
- Public consultation including Strand B members, manufacturers, SAG/SF

Final Project Plan: serves as basis for information needs in submission file

Current processes: Assessment phase



Lessons learned – Topic

- Topic selection:
 - Key criterion for national adaptation
 - indication-specific, not technology-specific
 - Implementation of a scoring system, where preferences are expressed by giving the scores in JA3?
- F2f scoping meetings
 - Useful
 - Huge coordinative/time-consuming task
 - Extend assessment duration considerably

Lessons learned - Timing

- Timing of assessments:
 - Less straight-forward than for pharma
 - Initiation by authoring agency
 - Updates to be tested in JA3?
 - Different types of assessments depending on stage of life-cycle (joint assessments vs collaborative assessments?)
- Submission file template:
 - Long time-frame needed for completing submission file
 - Focus on CUR and TEC domains
 - Development of short version of submission file/flexible use

Lessons learned - Quality

- Considerable experience gained leading to quality improvements
- Current QA mechanisms: dedicated reviewers and external experts (project plan, assessment); public consultation (project plan); manufacturers, patients, Strand B members (optional); medical editing; project management
- Further QA mechanisms: participation in the trainings organised by EUnetHTA AND active involvement in previous joint assessments? establishment of a pool of methodological EUnetHTA experts?

Lessons learned - Quality

- HTA Core Model:

- Flexible use of Core Model: less rigid division of rapid and full/comprehensive assessments
- Alignment with HTA Core Model

- Identification of further methodological guidance needed for non-pharma products in JA3

Thank you
Any questions?

