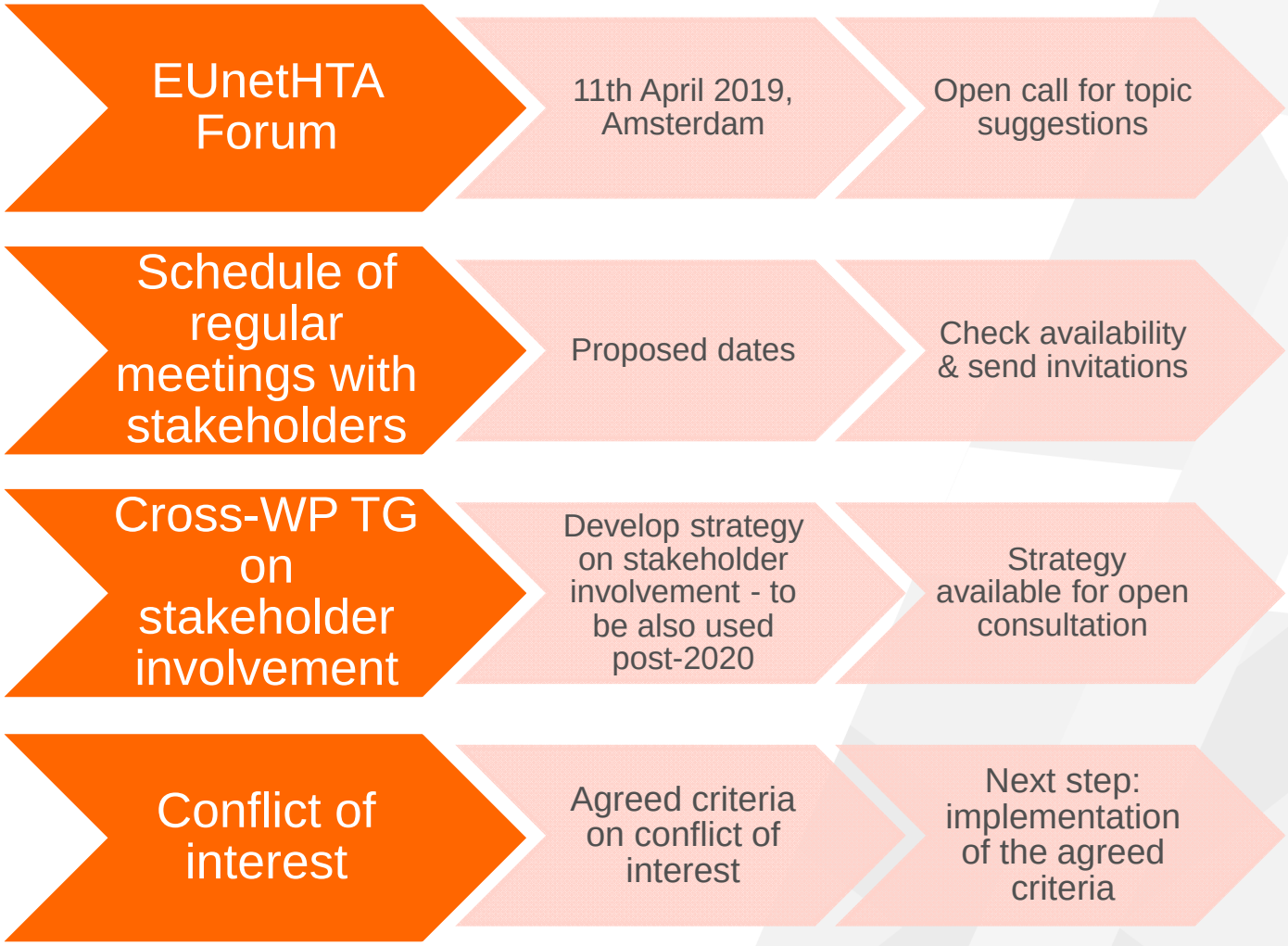
European Commission - HTA Network Stakeholder Pool Workshop

16.01.2019, Brussels

EUnetHTA Update on current and future stakeholder involvement

EUnetHTA JA3 Secretariat, Zorginstituut Nederland

Update on current and future stakeholder involvement



Schedule of regular meetings with stakeholders

Proposed meeting dates	Proposed meeting dates	Type of meeting	Location	Description
START	**END**			
14.02.2019	14.02.2019	E-meeting	SABA	EUnetHTA - Payers
21.03.2019	21.03.2019	Meeting	TBC	EUnetHTA - Health Care Providers
11.04.2019	11.04.2019	Meeting	Amsterdam	EUnetHTA Forum 2019
28.05.2019	28.05.2019	Meeting	TBC	2nd Workshop for Coordinated Activities on HTA and Medical Device Authorities
06.06.2019	06.06.2019	E-meeting	SABA	EUnetHTA - Patient & Consumer Organisations
14.11.2019	14.11.2019	E-meeting	SABA	EUnetHTA - Patient & Consumer Organisations
03.12.2019	03.12.2019	Meeting	Amsterdam	EUnetHTA 2019 Technical Meeting with Pharma Industry
13.02.2020	13.02.2020	E-meeting	SABA	EUnetHTA - Payers
26.03.2020	26.03.2020	E-meeting	SABA	EUnetHTA - Health Care Providers
02.04.2020	02.04.2020	Meeting	Amsterdam	EUnetHTA Forum 2020
07.05.2020	07.05.2020	E-meeting	SABA	EUnetHTA - Patient & Consumer Organisations

Task Group for Patient and Consumer (P&C) and Healthcare Provider (HCP) engagement

- Task Group (TG) established in September 2017
  - By EUnetHTA Secretariat

- Objective:
  - To support the development of a Patient, Consumer and Healthcare provider involvement process within WP4 and WP5.
  - Recommendations for patient engagement within EUnetHTA products

Stakeholder engagement

Early Dialogues and Assessments

WP4 – Joint Production

Pharmaceutical Technologies (PT)
&
Other Technologies (OT)

Stakeholders in assessment production (excerpt)?

Identification

- Contacting manufacturers
- Contacting patient organisations, medical societies

Scoping

- Scoping: involvement of patients, JA: scoping meeting with manufacturer(s); Review of PP by external experts & factual accuracy check by manufacturers

Assessment

- Manufacturer(s) provide evidence via submission file
- Review by external experts (currently)
- Option for factual accuracy check by manufacturer

Method	Other Technologies	Pharmaceuticals
Interview	OTCA10 Stool DNA testing/colorectal cancer	PTJA01 Midostaurin for AML
	OTCA12 C-reactive protein point of care testing	
	OTCA15 Irreversible electroporation liver, pancreatic cancer	PTJA03 Alecensa for NSCLC
Focus group	OTCA01 WCD	-
	OTJA08 glucose monitoring	
Patient input template	OTJA08 glucose monitoring	PTJA04 Sotagliflozin Diabetes
	OTCA07 cataract sugergy	
	OTCA18 regional hyperthermia	PTJA05 Enasidenib AML
	OTCA19 screening osteoporosis	
Other	OTCA04 MammaPrint (scoping meeting)	
	OTCA03 NIPT (input PP)	
	OTCA15 irreversible electroporation (review PICO)	

Summary: current patient involvement

Statistics

Patients involved in 9/18 in OT and 3/5 in PT assessments

Visibility

Description in methods section

Summary in results section

On EUnetHTA website

3 possible approaches for patient engagement

Approach	Method	Patient contribution deliverables	Patient's time investment	Conflict of Interest and Confidentiality issues
Call for patient input	✓ Call published on EUnetHTA webpage ✓ HTAi questionnaire template ✓ Proactively propose relevant association to contribute	- Feedback on scope of the assessment to be taken into account for PICO - HTAi questionnaire results to be published (appendix of the assessment report) - Mention in the final report reference to patient contribution	~ 1 day of work	Low
Interview	✓ HTAi questionnaire template ✓ Interview via phone	- Feedback on scope of the assessment to be taken into account for PICO - Summary of the interview to be part of appendix of the report - Mention in the final report reference to patient contribution	~ 1 day of work	High
Focus group	✓ Guided by moderator ✓ Based on HTAi questionnaire template ✓ Only for specific topics	- Minutes of the focus group meeting to be part of appendix of the report - Feedback on scope of the assessment to be taken into account for PICO - Mention in the final report reference to patient contribution	~ 2 days of work	High

Obstacles – patient involvement

- Identification of patients is burdensome and time consuming
- No response by patient organisations or no willingness to participate
- Representation of specific patient group
- Completion of DOICU form; industry funding of patient organisations not always accessible
- Tight timelines of assessments

Healthcare Provider involvement

- Current involvement:
  - 2 experts to review draft Project Plan & Draft Assessment Report
    - In almost all assessments, experts were involved
- Identification of experts is challenging
  - Conflict of interest
  - Burden of tasks
  - Tight timelines (pharma assessments)
- Focus on ‘fit-for-purpose’ engagement by EUnetHTA P&C/HCP TG
  - Discussion of different approaches
    - e.g. flexible involvement, pre-defined questions etc.
- Planned experts database

Outlook for stakeholder engagement

- Patient engagement
  - Discussions ongoing to have **open call for patient input** as a standardized approach for all assessments
    - If needed, to be completed with other preferred methods
  - EUnetHTA patient input template to be created
    - Based on HTAi template
  - Evaluation of patient involvement (questionnaire to patients and patient organisations)
- SOP on identification of stakeholder
- Revised methods for external expert involvement (currently being discussed)
- Working on ‘plain language summary’ for Assessment reports

WP5 – Scientific Advice

Maggie Galbraith, Project Manager WP5A, HAS
Stephanie Said, Project Manager WP5A, G-BA

Current stakeholder involvement – general input, product unspecific

June-July 2018: Public consultation on the procedure and briefing book template for Early Dialogues on Medical Devices

- Comments received from +10 organizations including several EUnetHTA partners and 6 stakeholder organizations (patients and professional organizations)
- Feedback received primarily related to transparency regarding the process, inclusion criteria for external stakeholders, how stakeholders are recruited and the iteration of advice.
- Official launch set for January 2019

Current stakeholder involvement – general input, product unspecific

November-December 2018: Consultation on Registry Quality Standards tool and Vision paper

- Feedback received from 12 HTAb partners, 7 external partners: EMA, 5 professional associations (EAHP, EFPC, EUPHA, ESC, ICON), and industry (COCIR). Additional feedback expected from EURORDIS…

- Many interesting comments that should support next version of the tool:
  - further guidance and requirement related to endpoint,
  - stage and frequency of registry assessment,
  - Sharing of confidential information from the registry for the assessment…

- Update REQueST and Vision paper using stakeholder comments then out to wide public consultation in early 2019.

Further Consultations to come…

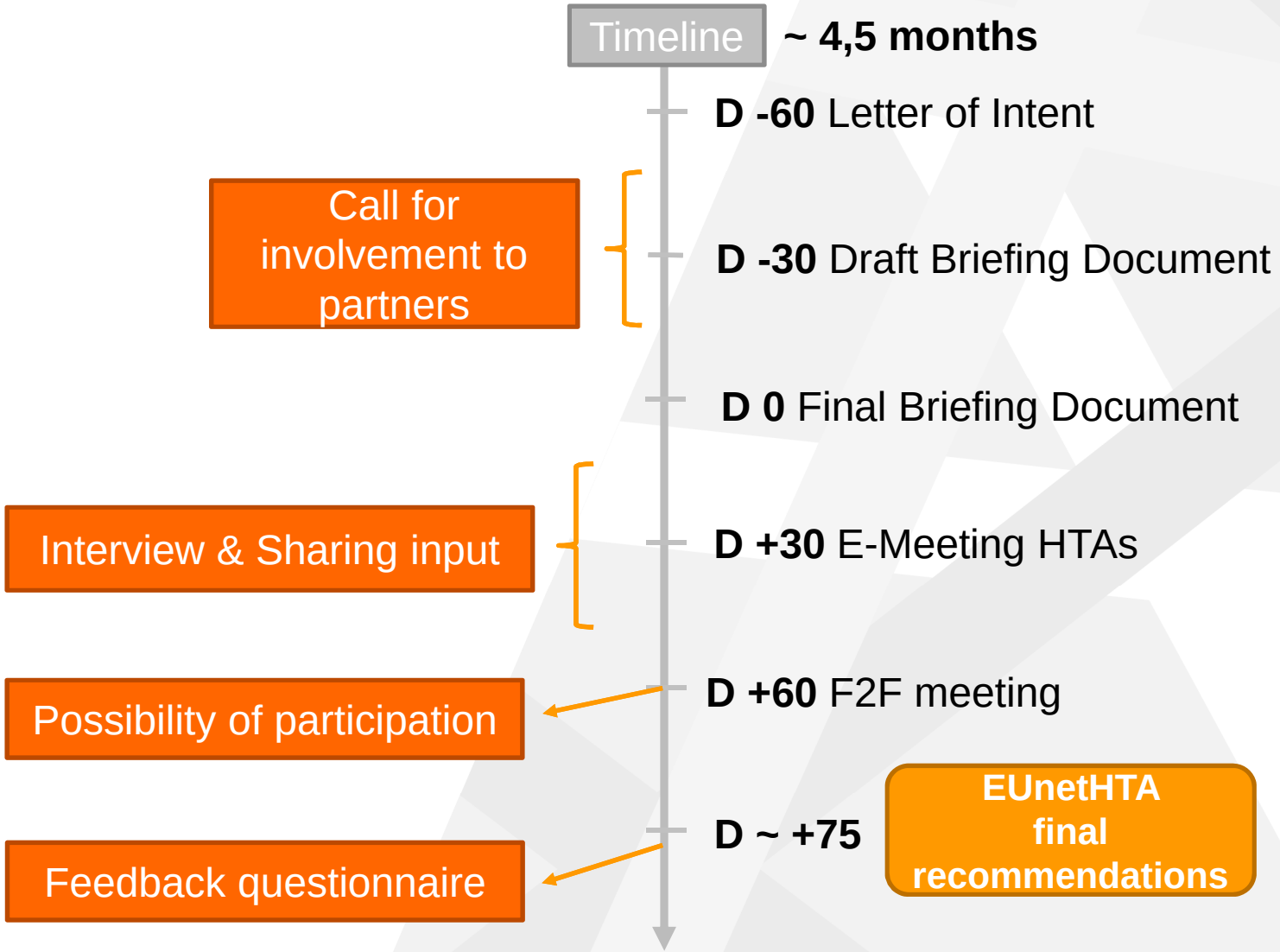
Strand A: Early Dialogues	
Updated ED Procedures for pharma	Q3 2019 Multi stakeholders consultation
Updated ED Briefing Book Template	Q3 2019 Industry consultation
Guidances for patients and HCP contribution for ED	Q2 - Q3 2019 Multi stakeholders consultation
Strand B: Post-Launch Evidence Generation	
Update REQueST	1Q 2019 Multi-stakeholders

Current stakeholder involvement – Early Dialogues (Pharma & MD)

Graduated approach to expert contribution

Approach	Patient contribution deliverables	Health Care Professional (HCP) contribution deliverables
Approach 1: Individual patient/HCP - interviewed regarding the disease and their experience	• Minutes of the interview • Patient contribution visible in final EUnetHTA recommendations • Feedback questionnaire	• Minutes of the interview • Feedback questionnaire
Approach 2: Approach 1 + discussion with local HTAB regarding submission file (without applicant)	• Minutes of the interview • Patient contribution visible in final EUnetHTA recommendations • Feedback questionnaire	• Minutes of the interview • Feedback questionnaire
Approach 3: Expert; Approach 1 + discussion with all participating HTABs regarding the submission file and participation in the F2F meeting with the applicant	• Minutes of the interview • Share final EUnetHTA recommendations • Feedback questionnaire	• Minutes of the interview • Feedback questionnaire

Current stakeholder involvement – Early Dialogues (Pharma & MD)



Current patient involvement – Early Dialogues

Experiences - systematic approach

13/17 EUnetHTA EDs with **patient contribution (~ 75%)**:

- 7x approach 1: **interviews with patients** (France, UK, Spain)
- 8x approach 2: **interviews with national patient representatives** (German patients' representative involved in any ED in which G-BA participates)
- 4x approach 3: **involvement of patient representatives from European patient organizations to overall process**

Paradigm Worshop on patient EDs contribution

Workshop last fall with other HTAB and representatives from Paradigm and HTAi PCIG to discuss patients contribution in Eds.

5 members of the EUnetHTA EDWP participated; exchanges demonstrated alignment of the 3 EUnetHTA approached with those of other HTAb

From this workshop, 4 priorities outlined

1. Patient recruitment process
2. Guidance on Patient Interviews
3. Minimum standards framework
4. Rationale for patient involvement in early dialogues

Current stakeholder involvement – Early Dialogues (Medical devices)

Only 1 Early Dialogue performed for Medical Devices so far:

- 4 of 8 participating HTAB included a **clinical expert**; 1 clinical expert participated in the closed HTAb meeting the morning of the F2F
  - 2 did not share the briefing book with the expert (corresponds to approach 1)
  - 2 shared the briefing book with the expert (corresponds to approach 2)
- Expert advice collected from each HTAb shared with other participating HTAb
- Expert contribution not included in the final recommendations

Future stakeholder involvement – Early Dialogues

Patients in Early Dialogues:
Dedicated group of HTABs to refine approach for patient involvement (procedure and tools) and produce guidance document

HCP in Early Dialogues:
Establish systematic approach

WP5 Lead and Co-Lead participation in EUnetHTA internal Patient & Consumer / Health Care Professionals Task Group:
Alignment on general principles on external stakeholder engagement, management of conflict of interest and payment

Thank you

Any questions?

Pharmaceutical EDs July 2017 through Nov 2018

45 Letters of Intent

Requests	Therapeutic field (from letter of intent)
2	Auto-immune disease/dysfunction
17	Cancer
3	Neurodegenerative disorder
3	Viral disease
17	Other

17 EUnetHTA EDs
(3 Multi-HTA + 14 Consolidated Parallel Consultations (PCC))

6 Cancer
2 Neurodegenerative disorder
1 Viral disease
8 Other

6 SME applicants
9 Orphan designations
4 ATMP

14 Completed (as of Nov 2018)

22 Individual Parallel Consultations
Including 1 vaccine
16 Completed
6 On-going

2 SME applicants
3 Orphan drugs
0 ATMP

4 withdrawn (by the Applicant, 1 resubmitted and accepted as PCI)
2 declined (procedure not followed; did not meet eligibility criteria for multi-HTA)