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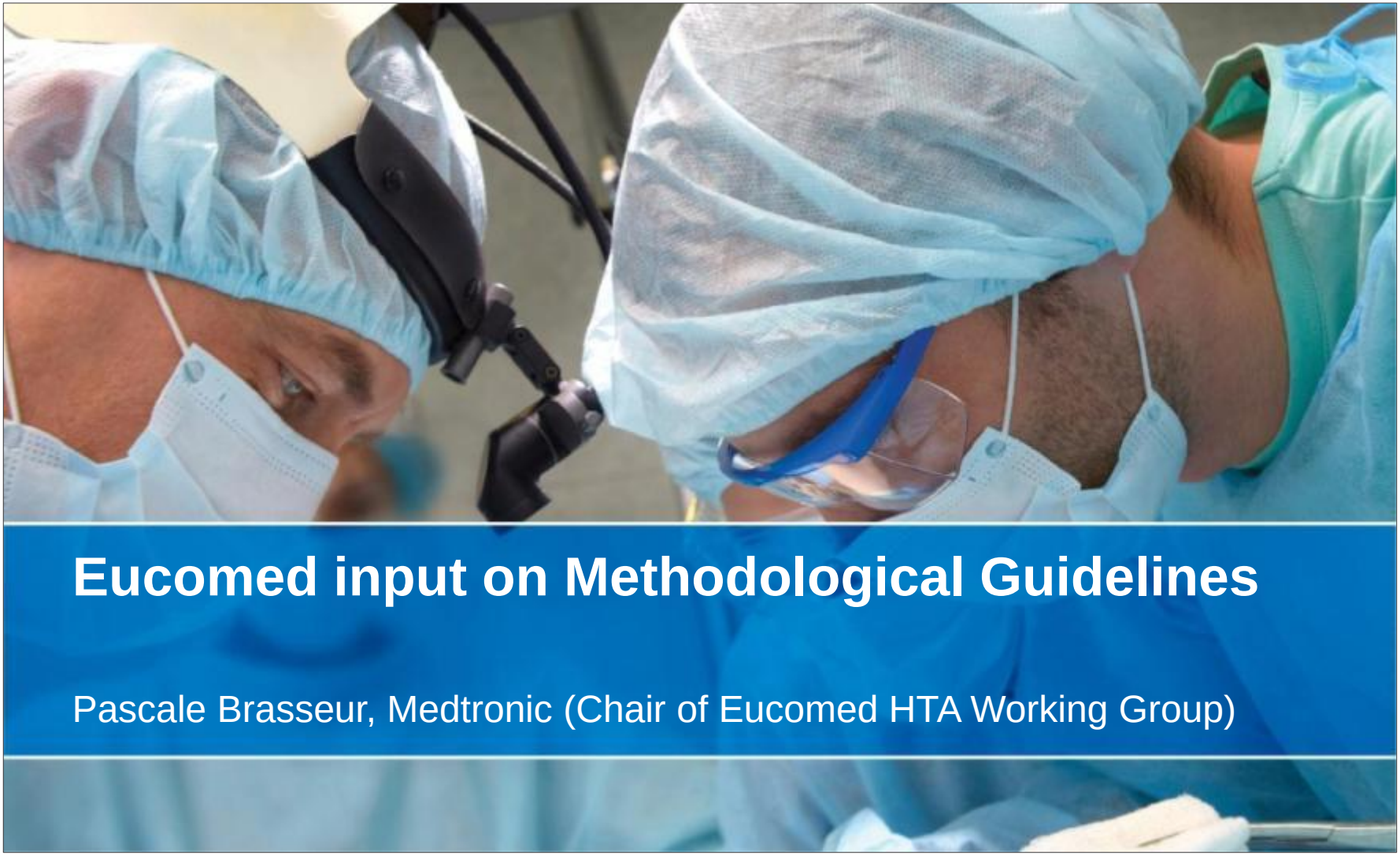

Eucomed input on Methodological Guidelines

Pascale Brasseur, Medtronic (Chair of Eucomed HTA Working Group)

1st expert meeting notes

- A face to face dialogue, collecting expertise at time of scoping , i.e. improve dialogue and understanding between the HTA community and medical technology industry
- Consider a face-to-face workshop at some stage of the guideline development, possibly instead of a written SAG consultation at the end of the project
- Consult physicians/professional societies/ industry statistical-clinical experts for useful insights to the methodological issues of assessing medical technologies.
- Involve experts on the assessment of specific types of medical technology

1st expert meeting notes

- Guidelines need to go beyond a compilation of available guidelines.

- It is important to tailor the content (or at least sufficiently explain the concepts and terminology) to the potential audiences of the guideline text to ensure outreach and understanding by a broader group, while still respecting the choice of the primary target group (i.e. the health technology assessors).

Specific comments

Update of 8 Guidelines (produced by EUnetHTA JA1)

- Is adaptation of guidelines from one technological group to another (very much different) appropriate and thorough?
- "New" guidelines may not properly support HTA assessors wishing to perform rapid REA on medical devices, and assessments performed following these guidelines will not appropriately inform decision makers on the true value and potential of medical devices.
- Eucomed is willing to work together with EUnetHTA and other stakeholders on this topic to ensure that European joint work is specific, fit-for-purpose and of high quality.

Specific comments

Guidelines on Internal Validity of non-RCTs

- ACROBAT-NRSI
  - New instrument. Will there be some validation?
  - Other tools already have international recognition
- Some incorrect statements
  - Inclusion of non-randomized studies will nearly always increase risk of bias
- What to do when both RCT and NRS are available?
- Quality of reporting can affect assessment of risk of bias

A few questions

- What will be the timing for other expected guidelines?
  - Safety
  - Disease-specific guidelines – Osteoarthritis
  - Personalized Medicine

- Is the use of the different guidelines developed being tracked?

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Back-up

Specific feedback

WP7-SG1 Update June 2015

Activity/Activity steps	Due date / Milestone (Since last e-meeting)	Status/Clarification of delays
Disease Specific Guideline on osteoarthritis	Change of deliverable : Report on Lessons learned and proposals for next JA	• Draft Report written at HAS and under current internal review before release to WP7 members and to SAG – 1st week of September 2015 • Revised version (HAS) on Week 41 (5-10th October 2015) • Public Consultation from Week 42 to Week 44 (by October 27th 2015) • Final Report on Week 45 (2-6th Nov 2015)

No update for SAG

Specific feedback

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No update for SAG

Specific feedback

WP7-SG3 Update Sept 2015

Activity/Activity steps	Due date / Milestone (Since last e-meeting)	Status/Clarification of delays
Elaboration of new general methodological guidelines	M21/Jun'14 (scheduled finalisation according to the original WP7-SG3 work plan for the first guidelines)	**First batch of guidelines** a. GL Internal validity of non-randomised studies (NRS) on interventions: published a. GL Economic evaluations: published b. GL Meta-analysis of diagnostic test accuracy studies: published

Specific feedback

Activity/Activity steps	Due date / Milestone (Since last e-meeting)	Status/Clarification of delays
Elaboration of new general methodological guidelines (cont.)	M23-M36 Aug '14 – Nov '15	**Second batch of guidelines** a. Personalised Medicine: internal consultation on reflection paper finished (82 comments from 9 partners), project in WP1 debate b. GL Medical Devices: internal consultation on draft guideline finished on 24th of August (139 comments from 12 partners), ongoing work on comments and preparation of a version for SAG /Public consultation c. GL Process of information retrieval … : published

Specific feedback

Activity/Activity steps	Due date / Milestone (Since last e-meeting)	Status/Clarification of delays
Update / Adaptation of JA1 methodological guidelines	M1-M36 Oct '12 – Nov '15	8 documents revised by three-persons-teams (language adaptations in regard to non-drug technologies) : Public and internal consultation on documents in a tracked-changes-view started on 26th of August "Safety" guideline: Supplemented version under internal review until 15th of September

Specific feedback

Methodol. Guideline	Start of SAG – Public consultation
1. Therapeutic Medical Devices 2. Supplemented/adapted JA1 guideline "Safety" 3. Check of wording changes in 8 JA1 guidelines	End of September 2015 Begin of October 2015 26th Aug - 9th of Oct ´15

THANK YOU