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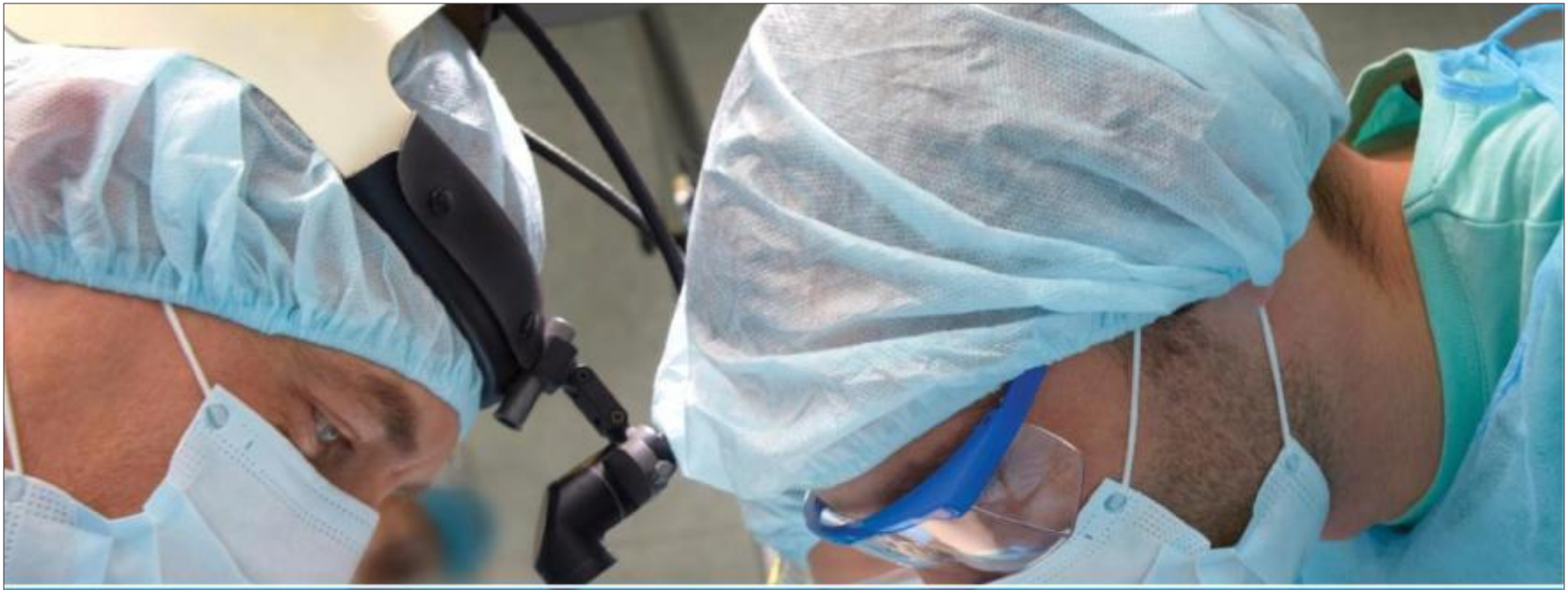


Eucomed experience of 5 EUnetHTA WP5b REA

Adrian Griffin I October 2015

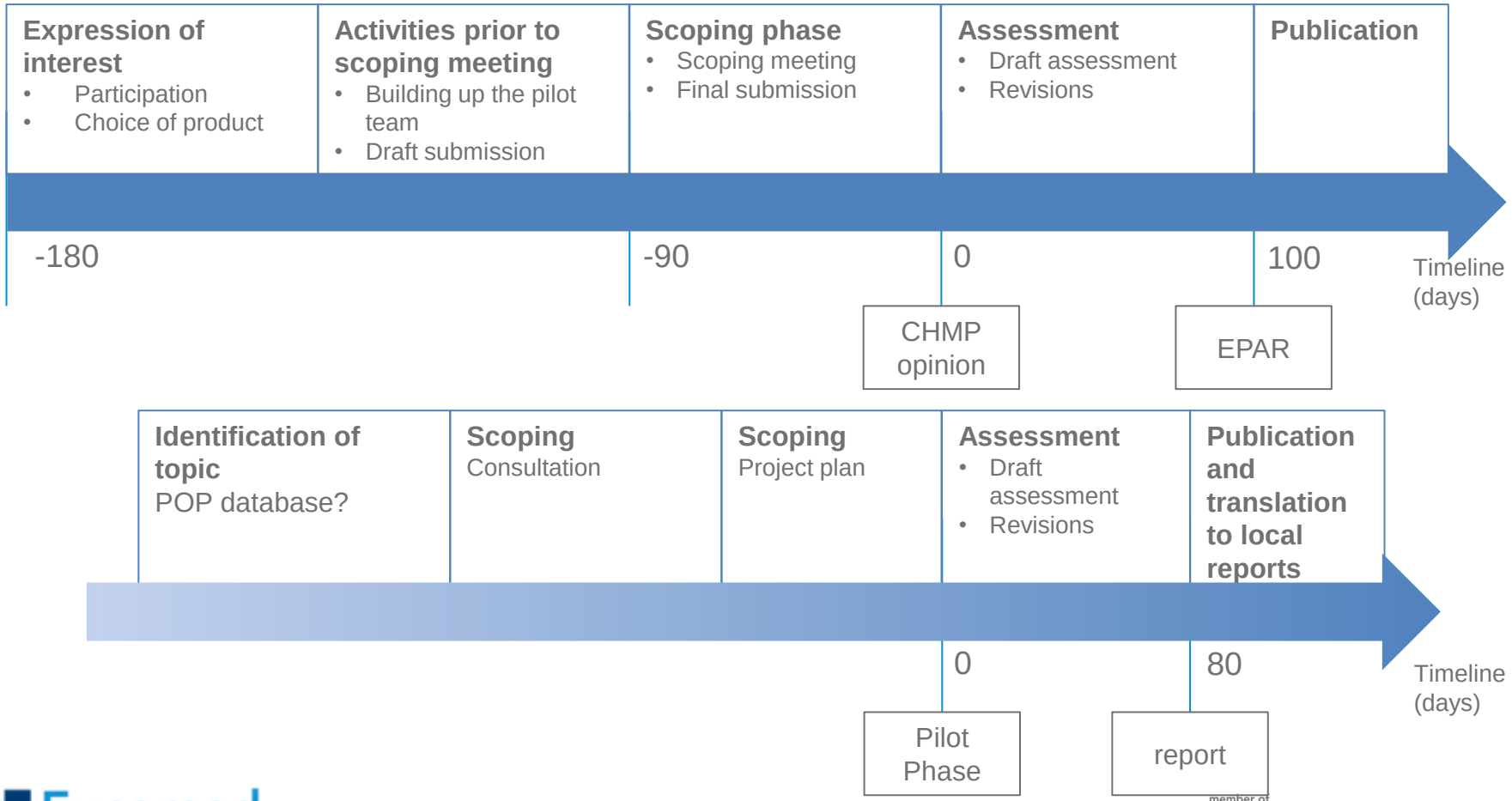
Work Package 5b Pilots

	PILOT	COMPANIES	CE mark	t (m)
1	Duodenal-jejunal bypass sleeve for the treatment of obesity	GI Dynamics	3 yrs	7
2	Renal denervation systems for treatment-resistant hypertension	St Jude Medical Boston Scientific Covidien Medtronic Recor Biosense Webster (JnJ)	1 yr 1 yr 1 yr 1 yr 1 yr -	10
3	Biodegradable stents for benign refractory oesophageal stenosis	ELLA-C	7 yrs	14
4	Balloon Eustachian tuboplasty for the treatment of Eustachian tube dysfunction	Spiggle and Theis Acclarent (JnJ)	3 yrs -	9
5	Implantable devices for the treatment of mitral valve regurgitation	Abbott Vascular Cardiac Dimensions Neochord	7 yrs 4 yrs 3 yrs	11
6	Mechanical thrombectomy in acute ischaemic stroke	Styker DePuy Synthes (JnJ)	5 yrs 3 yrs	9

Observations from Pilots

- Pilots covered SMEs and Large MedTech companies
- Topic Selection
  - No predictability/logic in time from CE marking
  - No predictability/logic in choice of single technology (P1) or therapeutic approach (P5)
- Stakeholder Engagement
  - Lack of consistency
    - Face to face at scoping (only 2 pilots)
    - Of which ability to agree scope before submission (only 1 pilot)
- Process
  - Faster than WP5a, without need / justification
  - Initial communication to general email account of company (*info@xxx.com*)
  - Time to develop submission 15-25 working days, + 5-8 days for clarification

Comparison of WP5a & 5b Pathways



Comparison of WP5 Work Packages

	Pharmaceuticals (WP5a)	MedTech (WP5b)
WHY	Inform local P&R	No clear decision pt.
WHEN	ASAP after CHMP opinion	No clear time pt.
DURATION	180 + 100 days	PLAN: ? + 80 Days ACTUAL: (90-180) + (120-330)
COMMUN-ICATION	To named responsible individuals	To generic mailbox on company website
HOW	Established Best Practice for Pharmaceuticals, acknowledged in EUnetHTA Guidelines	No recognition for MedTech specific Issues Cut & Paste: *"rewording of "assessment of pharmaceuticals" into "assessment of health technologies"*

Specific Feedback

Pilot 1

- An SME
- No capacity to address unplanned request for “European Assessment”
  - ‘Significant resource’ diverted to address request in short time span
  - Report was damaging for company – no recognition for innovative, SME business model
- To support SME business, the report should have;
  - Provided recommendations on evidence development
  - Suggested potential refinements to patient populations

Summary

- Potential topics cannot be foreseen
- Engagement requires ‘immediate’ resource
  - Resource usually deployed elsewhere on specific activities
- Projects are addressing no clear decision point for end-users
  - Difficult to continue to justify internal support to management

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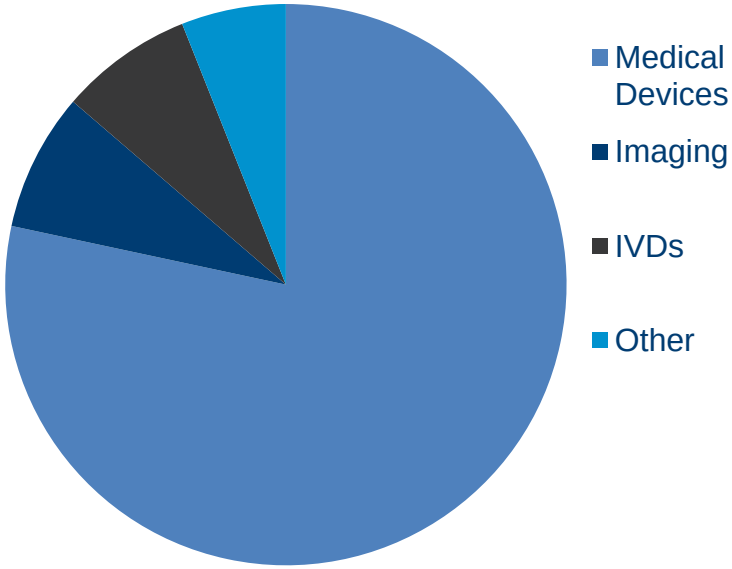
Context is Relevant

2014: 365 National HTA reports published in Europe

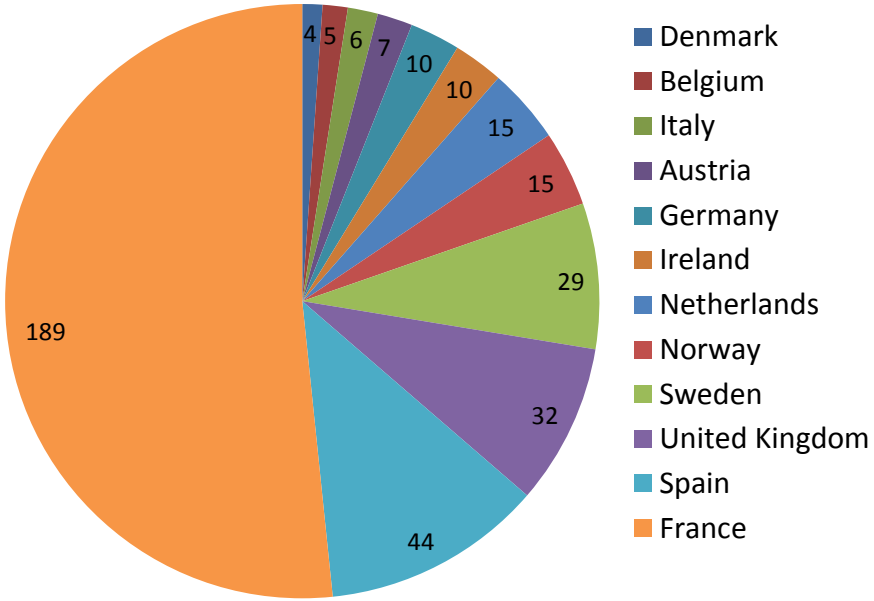
365 HTA reports were published in 2014

- 286 (78%) looking at medical devices
- 28 (8%) looking at IVDs
- 29 (8%) looking at imaging equipment
- 22 (6%) others



Reports were published in 12 European countries

- ➢ **80%** of in 4 Countries - FR, ES, UK, and SE
- ➢ **51%** of reports were published in France



Statistic based on Synergus database http://synergus.com/hta-update

Potential Efficiencies?

- Only **ONE** device/procedure was look at by 4 countries
  - Knee replacement - FR, UK, IE, ES
- **THREE** devices/procedures were looked at by 3 countries
  - Bariatric surgery – NO, SE, NL
  - TAVI – FR, ES, NL
  - Hip replacement – FR, UK, IE
- 13 procedures/devices were looked at by 2 countries – e.g.:
  - Percutaneous left atrial appendage occlusion (LAA) for prevention of stroke – FR, AU
  - Community based non-invasive ventilation, Community based invasive mechanical ventilation – NO, SE
  - Long-term support VAD – FR, SE
  - Cardiac pacing using dual-chamber pacemakers – FR, UK
- But SAME TOPIC did not mean SAME QUESTION

Same topic, but not the same question

Total knee replacement

- France: 3 brand specific reports looking at medical benefits for inclusion to the List of Reimbursable Products and Services
- UK: A randomised controlled trial of the clinical effectiveness and cost-effectiveness of different knee prostheses: the Knee Arthroplasty Trial
- Ireland: Arthroplasty for osteoarthritis of the knee
- Spain: Impact of the knee arthroplasty surgery on Spanish National Health System

Total Hip replacement

- France: 4 brand specific reports looking at medical benefits for inclusion to the List of Reimbursable Products and Services
- Ireland: Surgery for end-stage arthritis of the hip in adults
- UK: Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip (review of technology appraisal guidance)

Bariatric Surgery

- Norway: 2 reports on Long term effects of bariatric surgery and Surgical treatment of obesity
- Sweden: 2 reports on Bariatric surgery in adolescents with severe obesity and Is there support for obesity surgery in people with BMI 35-40 without other risk factors?
- Netherlands: Positioning Bariatric Surgery

Percutaneous aortic valve replacement (TAVI)

- France: 11 brand specific reports looking at medical benefits for inclusion to the List of Reimbursable Products and Services
- Spain: Cost effectiveness of percutaneous aortic valve replacement using prosthetic valve versus the standard surgical treatment
- Netherlands: Evaluation indicator protocol transcatheter aortic valve implantation

HTA in Europe performed at different time

Summary

- There is no obvious time point when a ‘significant number’ of member states are reviewing the same question at the same time
- Variations in time and focus of question are related to local context, priorities, and funding pathways
- It is not a question of Rapid v Full; it is a Question of ‘What is Relevant’
  - This has not been addressed in JA2 / current pilot activity
- What’s Potentially useful?
  - A toolkit to assist local reviews when they’re required: AdHopHTA?
  - Reviews that ‘identify’ evidence needs
  - Then propose and facilitate options for addressing evidence gaps

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Thank You