

# EUnetHTA

## Production of EUnetHTA assessments: Current procedures and timelines

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# News

EUnetHTA website: Get involved → Industry → MD, diagnostics, screening technologies

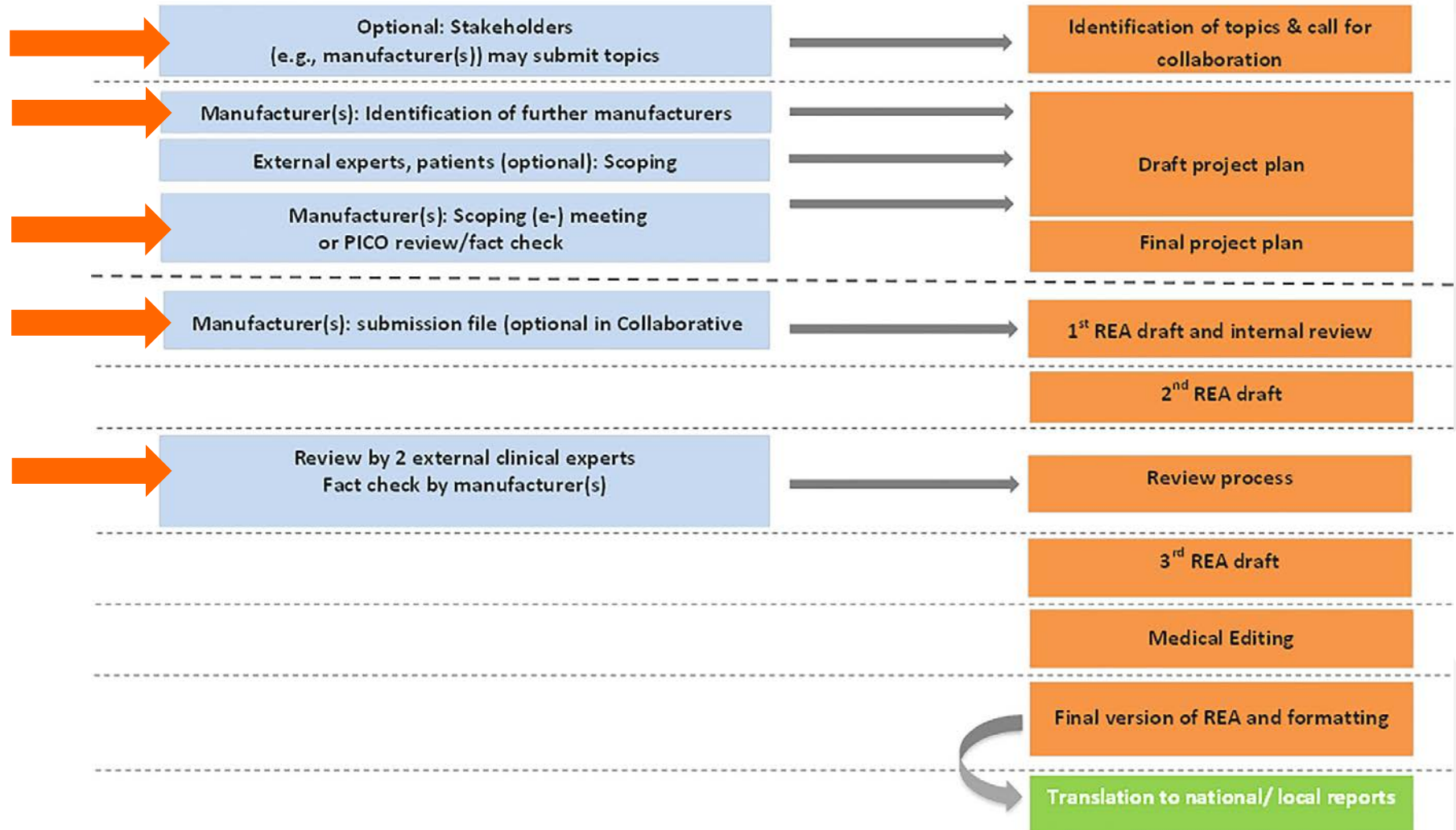
*FAQs and videos are published:*

<https://www.eunetha.eu/services/submission-guidelines/other-technologies-submission/>

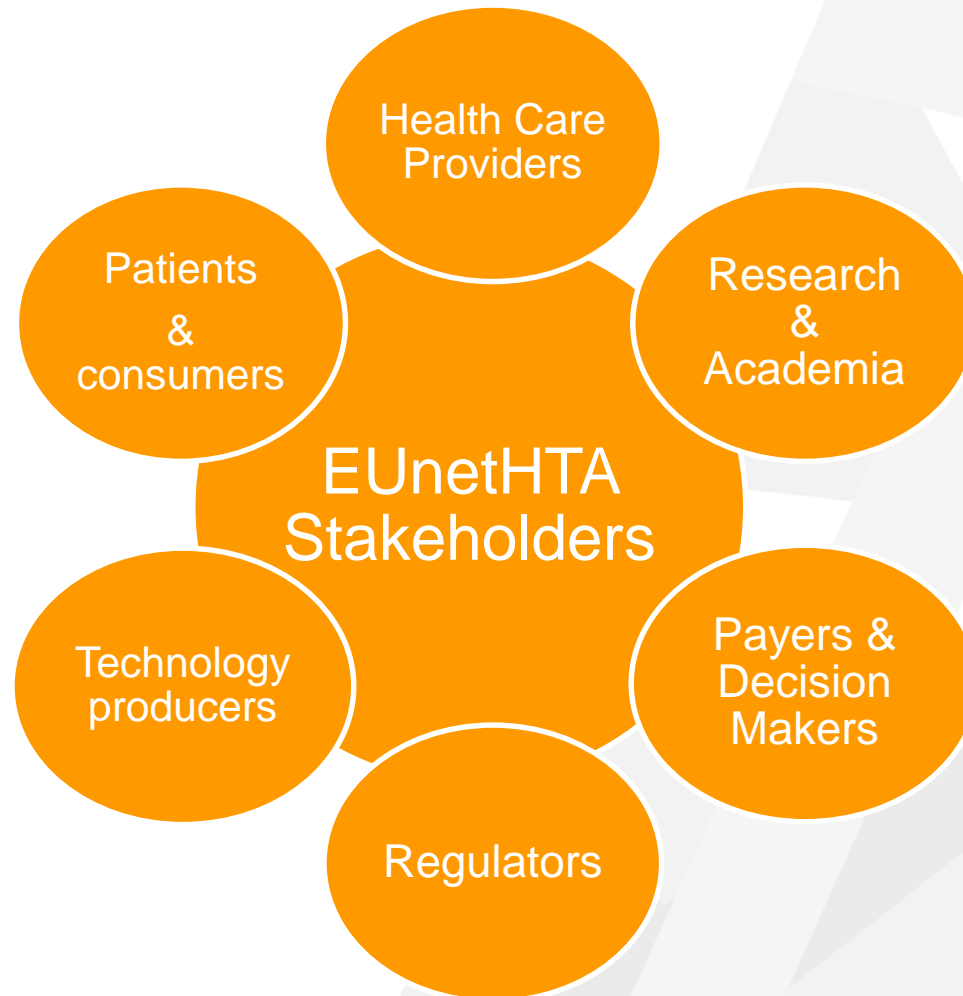
# Production process

## Stakeholder involvement

## Rapid REA process



# EUnetHTA Stakeholders: who



## Manufacturer involvement

### Other technologies

- Commenting on **preliminary PICO**
- 3/13: **Scoping meeting** with manufacturer
- 8/13: **Factual accuracy check** of draft project plan
- 12/13: **Factual accuracy check** of draft assessment
- 12/13: **Submission dossier**
- 1/13: unsuccessful involvement



# Which manufacturers were involved (1/2)?

Project ID	Manufacturer
OTCA01 (WCD)	ZOLL Medical Corporation
OTCA02 (antibacterial coated sutures)	Ethicon Johnson & Johnson Company Int.
OTCA03 (NIPT)	Sequenom Laboratories, San Diego, CA, USA Ariosa Diagnostics Inc./Roche Sequencing Solutions Inc., San Jose, California, USA Natera®, San Carlos, CA, USA Premaitha Health, PLC, London, UK Illumina Inc., San Diego, CA, USA Imegen Instituto de Medicina Genómica, Valencia, Spain Vanadis Diagnostic, Perking Elmer Inc., Sweden Genesupport SA, Freiburg, Switzerland NIPD Genetics, Nicosia, Cyprus Berry Genomics Co. Ltd., China Igenomix SL, Spain Genoma Laboratories, Rome, Italy Ebios Futura S.r.l., Cueno, Italy Sorgente Genetica S.r.l., Italy Mutiplicom NV (Agilent Technologies, CA, USA) LifeCodexx AG, Konstanz, Germany LabCorp Inc., North Carolina, USA BGI Diagnostics Technology Co. Ltd., Shenzhen, China
OTCA04 (MammaPrint)	Agendia, The Netherlands

# Which manufacturers were involved (2/2)?

Project ID	Manufacturer
OTCA05 (rTMS)	Neurosoft, Russia Mag&More, Germany
OTCA06 (TAVI)	Edwards Lifesciences Medtronic
OTCA07 (FLACS)	Alcon (Novartis) - LenSx Laser System
OTJA08 (glucose monitoring)	Abbott Diabetes Care Dexcom, Inc. Medtronic
OTCA09 (HIFU)	EDAP TMS
OTCA11 (3D printing)	Johnson & Johnson Materialise Raomed
OTCA12 (CRP-POCT)	Abbott (formerly Alere), Oslo, Norway Biosurfit, Lisbon, Portugal Eurolyser Diagnostica, Salzburg, Austria Medix Biochemica, Espoo, Finland Orion Diagnostica Oy, Espoo, Finland Radiometer Medical ApS, Copenhagen, Denmark RPS Diagnostics, Sarasota, Florida, USA
OTCA14 (Robotic surgery)	Intuitive Surgical
OTCA16 (Bioresorbable Stents)	Reva Medical, San Diego, CA, USA Biotronik, Bülach, Switzerland

# Submission dossier from manufacturers

- Submission dossier (established in JA2): reflects national evidence requirements for reimbursement in Europe
- Focus on TEC, CUR domains
- Non-confidential information
- Timeline for sending back completed dossier: 30 working days
- Submission requirements document: aim to publish dossier together with final assessment (without redaction)



# Factual accuracy check by manufacturers

- Purpose: to highlight any errors or inaccuracies with the factual content of the document that are related to the technologies under assessment.
- Any comments affecting the interpretation of data (data presentation, description and conclusions of the report) are outside the scope of a fact check and won't be considered/answered.
- 2nd draft project plan and 2nd draft assessment
- Confidentiality Undertaking (CU) form (3 days prior)
- Timeframe: 5 working days
- Comments/Answers are published
- During JA3: optional

# Thank you!

# Questions?

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