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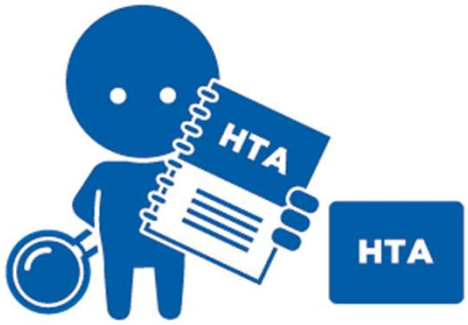
HTA in Austria

National and international perspective



Claudia Wild, Director of AIHTA

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National perspective

HTA as decision support

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Potential Utilization of HTA

* Planning of large investments (equipment)

* Planning of Investments in prevention-programmes

* Benefit catalogues: drugs, medical inteventions

* Quality assurance/-management

* Disinvestment

Actual utilization in Austria

*Planning: utilization of large equipment and need assessment of n of equipment: PET, radiotherapy, etc.

*Evidence: lung cancer, colon, screening, tools for risk-assessment, HPV-vaccination, mother-child programme: social risks etc.)

*Hospital benefit catalogue: new (high risk) medical inteventions, high-cost drug assessments (oncologic drugs, CAR-T, SMA, ATMP)

*dementia registries, SMA-/ CAR-T RWE

* not systematic

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Examples (incl. methodology)

1. Planning: need assessment
2. Investment in prevention-programmes
3. Benefit- catalogue: hospital interventions
4. Quality assurance/ - management
5. Disinvestment

1. Planning

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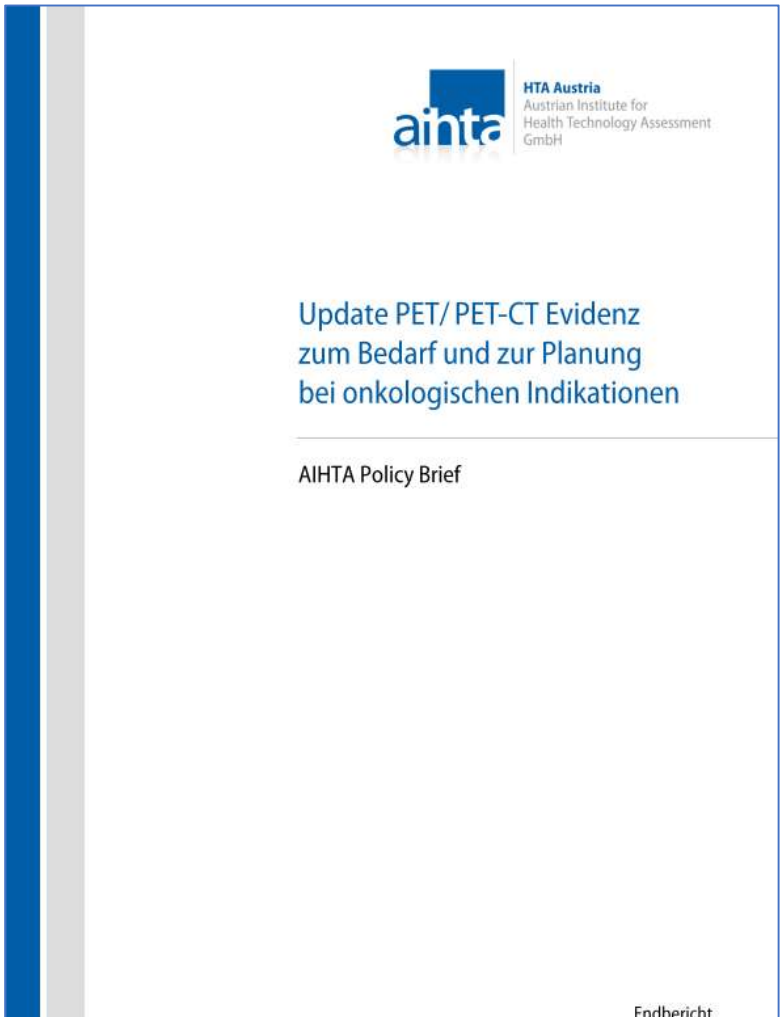
Methodology: Synthesis of evidence-based clinical guidelines



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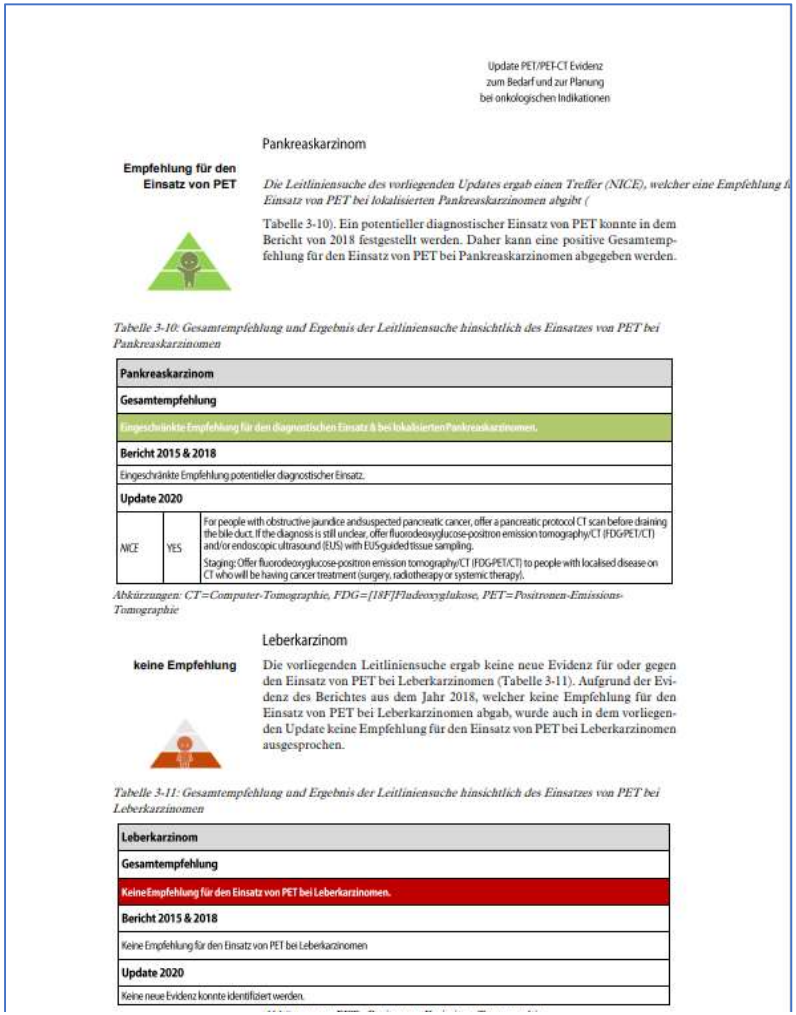
Update PET/ PET-CT Evidenz
zum Bedarf und zur Planung
bei onkologischen Indikationen

AIHTA Policy Brief

Endbericht



Update PET/PET-CT Evidenz
zum Bedarf und zur Planung
bei onkologischen Indikationen

Pankreaskarzinom

Empfehlung für den Einsatz von PET

Die Leitliniensuche des vorliegenden Updates ergab einen Treffer (NICE), welcher eine Empfehlung f[ür den] Einsatz von PET bei lokalisierten Pankreaskarzinomen abgibt (

Tabelle 3-10). Ein potentieller diagnostischer Einsatz von PET konnte in dem Bericht von 2018 festgestellt werden. Daher kann eine positive Gesamtempfehlung für den Einsatz von PET bei Pankreaskarzinomen abgegeben werden.

Tabelle 3-10: Gesamtempfehlung und Ergebnis der Leitliniensuche hinsichtlich des Einsatzes von PET bei Pankreaskarzinomen

Pankreaskarzinom		
Gesamtempfehlung		
Eingeschränkte Empfehlung für den diagnostischen Einsatz b bei lokalisierten Pankreaskarzinomen.		
Bericht 2015 & 2018		
Eingeschränkte Empfehlung potentieller diagnostischer Einsatz.		
Update 2020		
NICE	YES	For people with obstructive jaundice and suspected pancreatic cancer, offer a pancreatic protocol CT scan before draining the bile duct. If the diagnosis is still unclear, offer fluorodeoxyglucose-positron emission tomography/CT (FDG-PET/CT) and/or endoscopic ultrasound (EUS) with EUS-guided tissue sampling. Staging: Offer fluorodeoxyglucose-positron emission tomography/CT (FDG-PET/CT) to people with localised disease on CT who will be having cancer treatment (surgery, radiotherapy or systemic therapy).

Abkürzungen: CT=Computer-Tomographie, FDG=[18F]Fludeoxyglukose, PET=Positronen-Emissions-Tomographie

Leberkarzinom

keine Empfehlung

Die vorliegenden Leitliniensuche ergab keine neue Evidenz für oder gegen den Einsatz von PET bei Leberkarzinomen (Tabelle 3-11). Aufgrund der Evidenz des Berichtes aus dem Jahr 2018, welcher keine Empfehlung für den Einsatz von PET bei Leberkarzinomen abgab, wurde auch in dem vorliegenden Update keine Empfehlung für den Einsatz von PET bei Leberkarzinomen ausgesprochen.

Tabelle 3-11: Gesamtempfehlung und Ergebnis der Leitliniensuche hinsichtlich des Einsatzes von PET bei Leberkarzinomen

Leberkarzinom
Gesamtempfehlung
Keine Empfehlung für den Einsatz von PET bei Leberkarzinomen.
Bericht 2015 & 2018
Keine Empfehlung für den Einsatz von PET bei Leberkarzinomen
Update 2020
Keine neue Evidenz konnte identifiziert werden.

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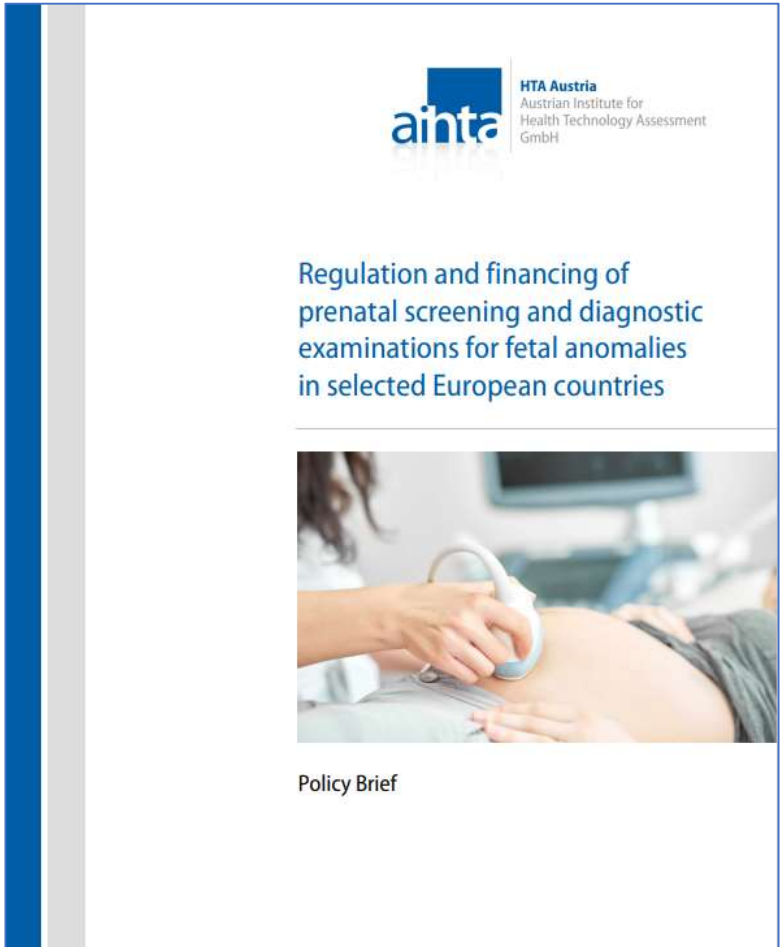
2. Prevention and Screening

Methodology: Overview of Policy Documents



	DE	CH	NL	UK	NO	IT
Setting of prenatal screening/diagnostic tests (hospitals, doctor's practice, other)						
FTS/CT	in hospitals, doctor's practices, prenatal centres (mostly outpatient)	in hospitals, doctor's practices, ultrasound centre	n/a (not offered anymore since 10/2021)	in hospitals	n/a (not offered anymore since 09/2021)	in hospitals, doctor's practices, private clinics
NIPT	in hospitals, doctor's practices, prenatal centres (mostly outpatient)	in hospitals, doctor's practices, ultrasound centre	in midwifery practices, in hospitals (women with increased risk)	in hospitals	in hospitals	in hospitals, doctor's practices, private clinics
AC/CVS	in hospitals, prenatal centres, institutes with a special qualification	in hospitals, doctor's practices (specialised in feto-maternal medicine), ultrasound centre	in hospitals (centres for prenatal diagnosis)	in hospitals	in hospitals	in hospitals, doctor's practices, private clinics
Second-trimester US	in hospitals, doctor's practices, prenatal centres (mostly outpatient)	in hospitals, doctor's practices (specific US diploma), ultrasound centre	in centres for prenatal ultrasound (often part of a midwifery practice), in hospitals	in hospitals, at community scanning clinics for low-risk women	in hospitals	in hospitals, doctor's practices, private clinics

Abbreviation: AC – amniocentesis, CH – Switzerland, CT – Combined Test, CVS – chorionic villus sampling, DE – Germany, FTS – First Trimester Screening, IT – Italy, n/a – not applicable, NIPT – non-invasive prenatal test, NL – Netherlands, NO – Norway, UK – United Kingdom, US – ultrasound

** women can choose if they want to have other findings than T21, T18 and T13 reported*

	DE	CH	NL	UK	NO	IT
Offer of prenatal screening/diagnostic tests (for all pregnant women, women with risk factors, other criteria)						
First Trimester Screening (FTS)/ Combined Test (CT)	for all pregnant women (but offered on a private basis, "IGeL")	for all pregnant women	n/a (not offered anymore since 10/2021)	for all pregnant women	n/a (not offered anymore since 09/2021)	for all pregnant women
Non-Invasive Prenatal Test (NIPT)	currently offered on a private basis, will be included in the national programme in 2022 for women with specific criteria (test scope: T21, T18, T13)	*second-line* screening for pregnant women with increased risk from FTS/CT >1:1,000 (test scope: T21, T18, T13)	*first-line* screening for all pregnant women (test scope: whole-genome sequencing*)	*second-line* screening for pregnant women with increased risk from CT >1:150 (test scope: T21, T18, T13)	*second-line* screening for pregnant women with risk factors (e.g., age >35, hereditary risks, abnormal US findings) (test scope: T21, T18, T13)	depending on the region
Amniocentesis (AC)/ chorionic villus sampling (CVS)	for pregnant women with increased risk (e.g., maternal age, abnormal US findings)	for pregnant women with increased risk (e.g., risk of >1:380 in FTS/CT, positive NIPT, abnormal US findings, family history)	for pregnant women with increased risk based on NIPT, prior pregnancy or abnormal US findings	for pregnant women with risk factors (previous history, increased risk in CT or NIPT, abnormal US findings)	for pregnant women with risk factors	for pregnant women with risk factors (e.g., high risk at CT or NIPT, maternal age, known genetic or familial condition, abnormal US findings)
Second-trimester ultrasound (US) screening	for all pregnant women	for all pregnant women	for all pregnant women	for all pregnant women	for all pregnant women	for all pregnant women
Financing of prenatal screening/diagnostic tests (fully or partially publicly reimbursed, self-paid)						
FTS/CT	completely self-paid ("IGeL – individuelle Gesundheitsleistung")	fully publicly reimbursed	n/a (not offered anymore since 10/2021)	fully publicly reimbursed	n/a (not offered anymore since 09/2021)	fully publicly reimbursed
NIPT	currently, completely self-paid; introduction as a health insurance benefit in 2022 (criteria: increased risk from another test, high psychological burden; no detailed list of risk factors)	fully publicly reimbursed for women with increased risk (see above)	partially publicly reimbursed/co-payment of 175€ for pregnant women without risk factors; for women with increased risk: fully reimbursed	fully publicly reimbursed if done as contingent screening (see above)	fully publicly reimbursed for women with risk factors (see above)	depending on the region
AC/CVS	fully publicly reimbursed for women with risk factors	fully publicly reimbursed for women with risk factors	fully publicly reimbursed for women with risk factors	fully publicly reimbursed for women with risk factors	fully publicly reimbursed for women with risk factors	fully publicly reimbursed for women with risk factors
Second-trimester US	fully publicly reimbursed for women with risk factors/ suspicious findings	fully publicly reimbursed	fully publicly reimbursed	fully publicly reimbursed	fully publicly reimbursed	fully publicly reimbursed

Methodology: systematic reviews on evidence and economic analyses

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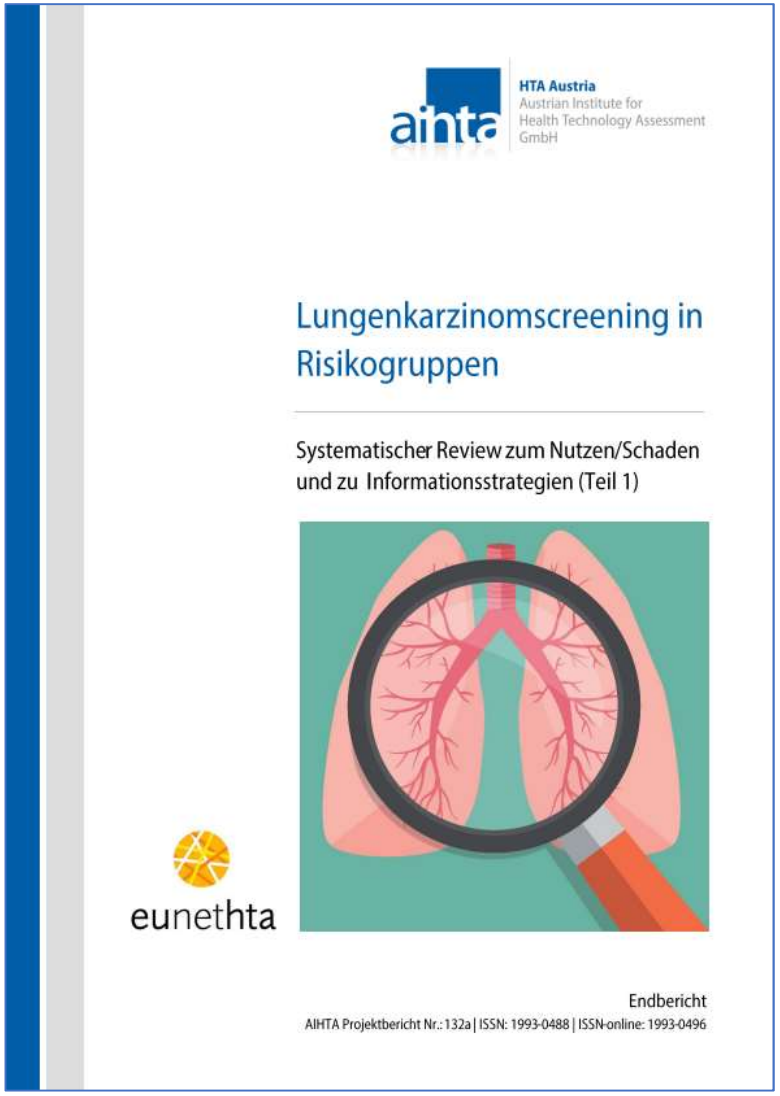

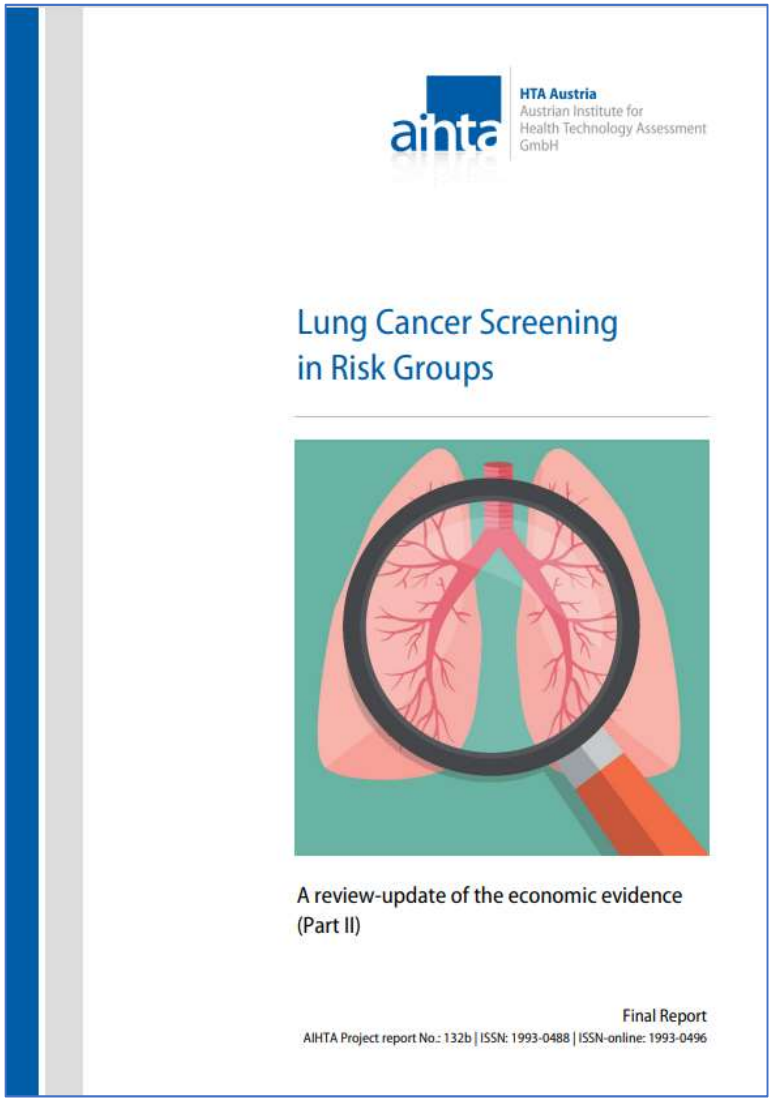

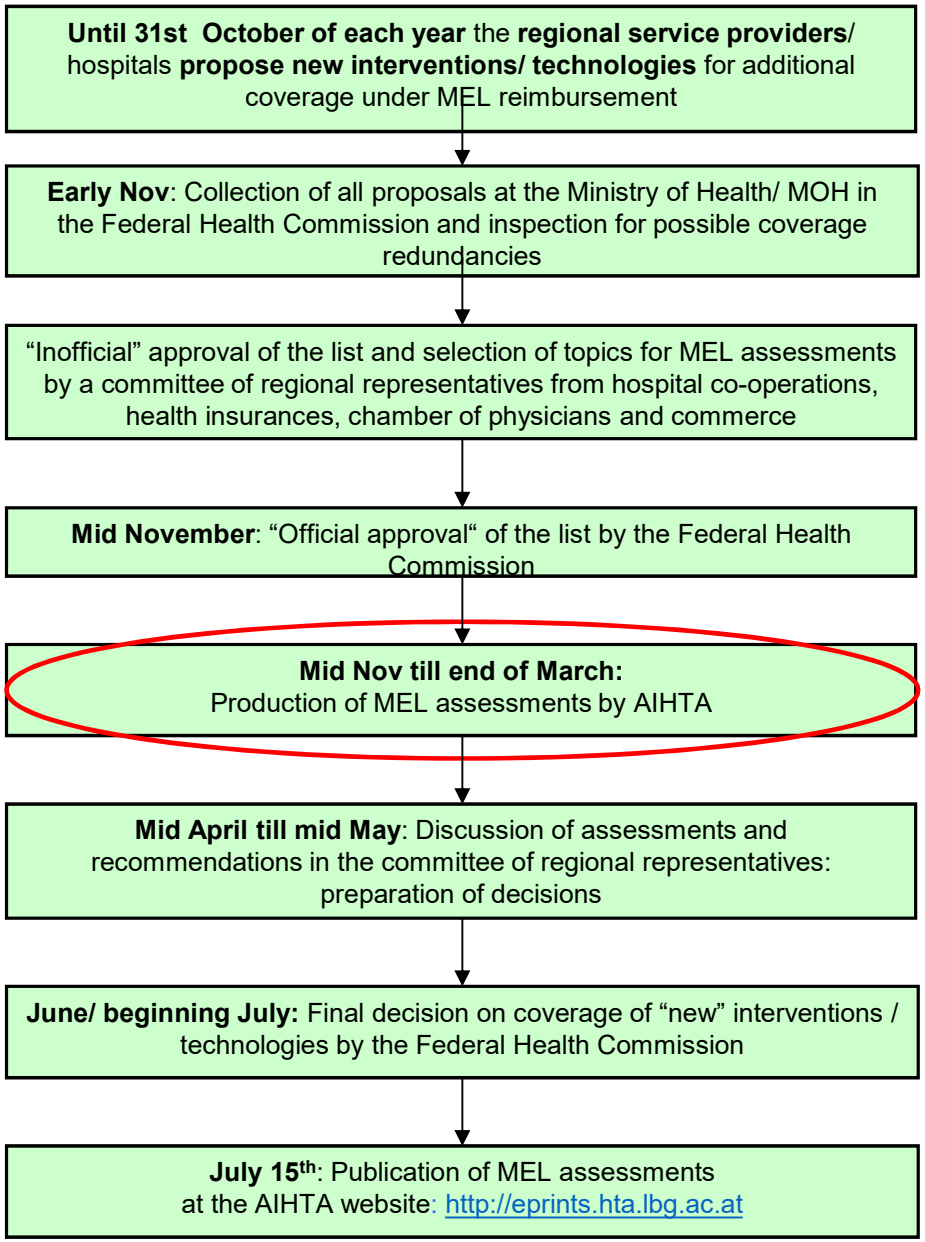

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3. Hospitals Benefit Catalogue

Annual process in Austria (MEL):

→ Service provider/ hospitals propose (about 5-10) new interventions to MoH

→ Until 2007 „eminence-based" decisions, since then „evidence-based"

→between mid November till end March (around 5-8 + updates; NO drugs).

→Process AND products are transparent

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GRADE: Recommendation key & results

1	**Recommendation, acceptance**. There is clear evidence for a net benefit of the intervention.
2	**Rejection**. There is clear evidence of no net benefit of the intervention.
3	**Recommendation with limitations**. There is indication of a net benefit. Further evidence might have influence on the re-evaluation of the intervention at a later date.
4	**Preliminary rejection**. There is not enough evidence to assess the net benefit of the intervention at this time.

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Methodology: Evidence synthesis + recommendations

- 2008-2021: 124 Systematic Reviews
  - 2/3 new interventions
  - 1/3 Updates
  - often MTA (interventions with several medical devices)
  - But also STA (single technology assessments)
- 2008-2020 Decisions: 107 von 118 (90,1%) consistency between HTA-recommendations and policy decisions

4. RWE for Quality assurance

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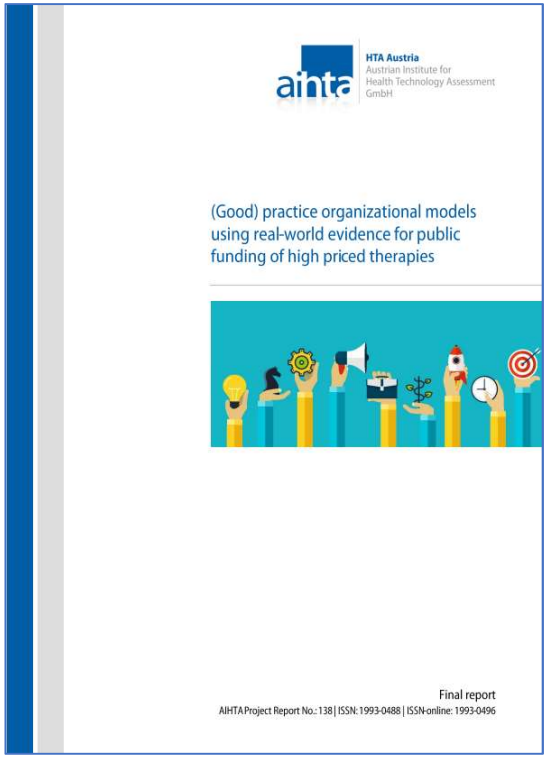
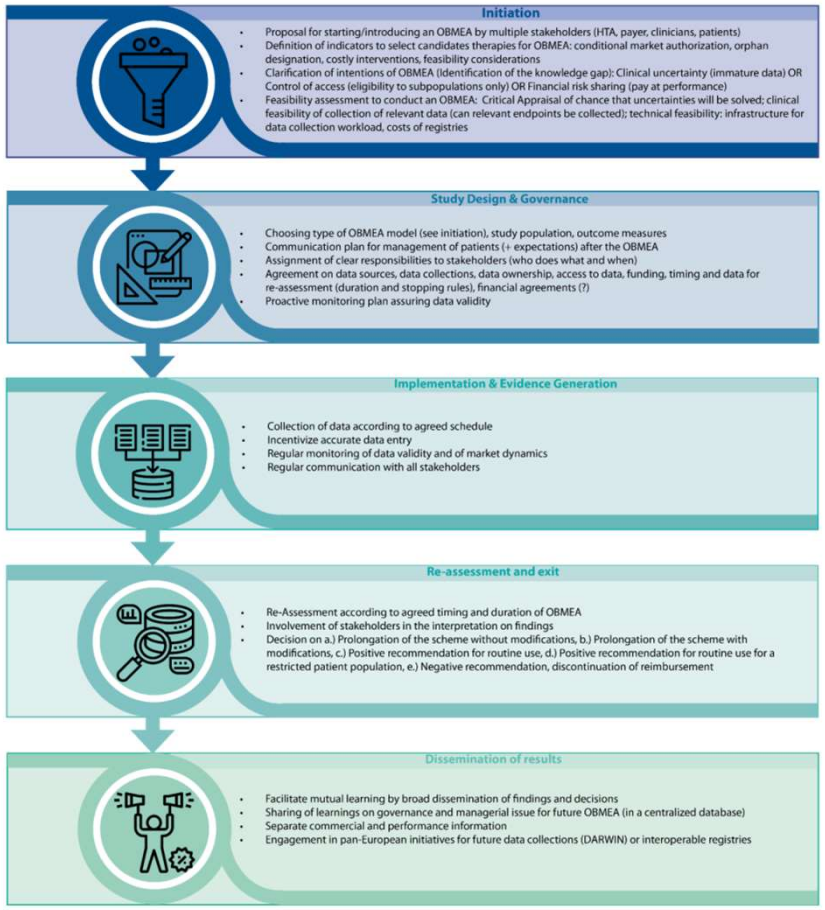
Methodology: Literature Review + interviews





https://eprints.aihta.at/1329/1/HTA-Projektbericht_Nr.138%20.pdf

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5. Disinvestment

(happens more implicitly)

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Conclusion

1. Blank spot in Austria: decentralization (in regional hospitals) of decisions on high-cost medicines (CAR-T, SMA, oncological drugs) – NO Austrian-wide benefit catalogue !
2. Methodology: there is not one size fits all methodology (evidence syntheses, overview of reviews or policy documents, syntheses of Eb-Clinical Guidelines, qualitative narrative review, etc.) – transparency is key !

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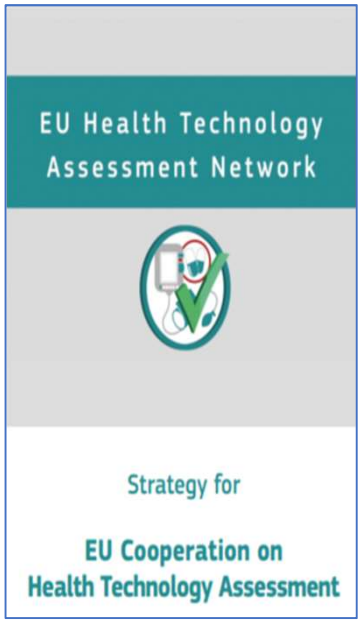
International perspective

EU HTA cooperation



JA1 (2010 – 2012)
JA2 (2012 – 2015)
JA3 (2016 – 2021)

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Ca 700-800 ongoing projects in Europe (at any time), 50% in UK

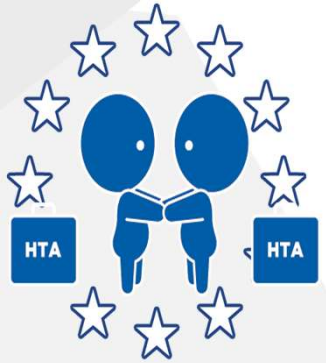
10% identical topics (same time, same tech, STA, mostly pharma)

30% similar (same indication, MTA)

Table 1. Overview of Selected Technologies

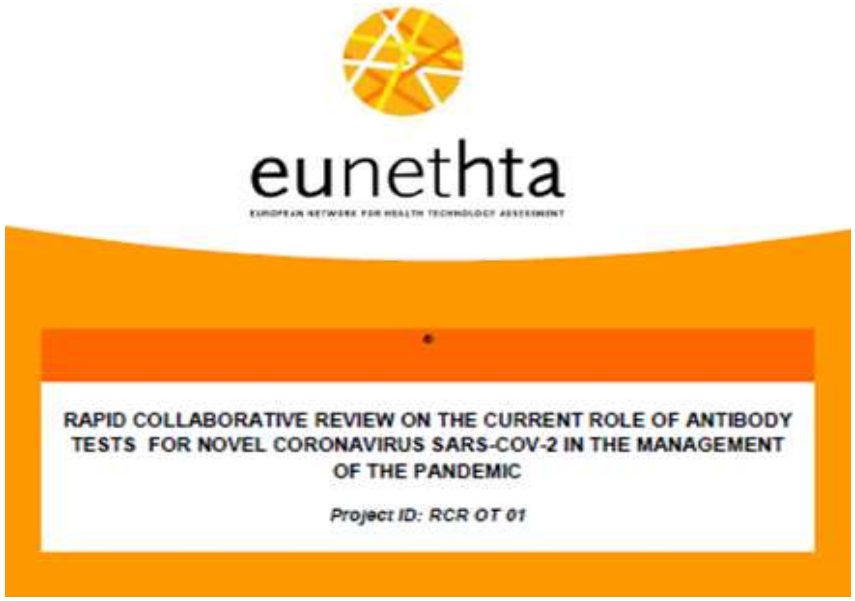
Technology	Taxonomic position[a]	Risk group[b]	1st CE-mark	No. of products (with CE-mark)	Time range	No. of HTAs
Sacral nerve stimulation (SNS)	32	IV	1994	2	2004-2016	9
Intraoperative radiation therapy (IORT)	27	IIb	1999	6	2006-2015	7
Robotic surgery (RS)	27	IIb	1999	2	2007-2015	13
High intensity focused ultrasound (HIFU)	27	IIb	2000	10	2003-2014	13
Implantable cardiac resynchronization therapy and defibrillator (CRT-P/D)	14,32	IV	2001	8	2003-2015	12
Lumbar total disc replacement (LTDR)	29	III	2001	4	2007-2016	8
Drug-eluting stents (DES)	29	III	2002	12	2004-2015	15
Intensity-modulated radiation therapy (IMRT)	27	IIb	2002	7	2003-2015	12
Transcatheter aortic valve implantation (TAVI)	29	III	2007	5	2008-2015	22
MitraClip®	29	III	2008	1	2010-2016	9
Total no. of reports						120

Note. No., number, number of identified HTA reports by technology from January 2003- July 2016, Time range from first to latest assessment.
[a]Henschke C., Panteli D., Perleth M. & Busse R. Taxonomy of medical devices in the logic of health technology assessment. *Int J Technol Assess Health Care*. 2015;31:324-330.
[b]European Parliament and Council of the European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. L117, 2017

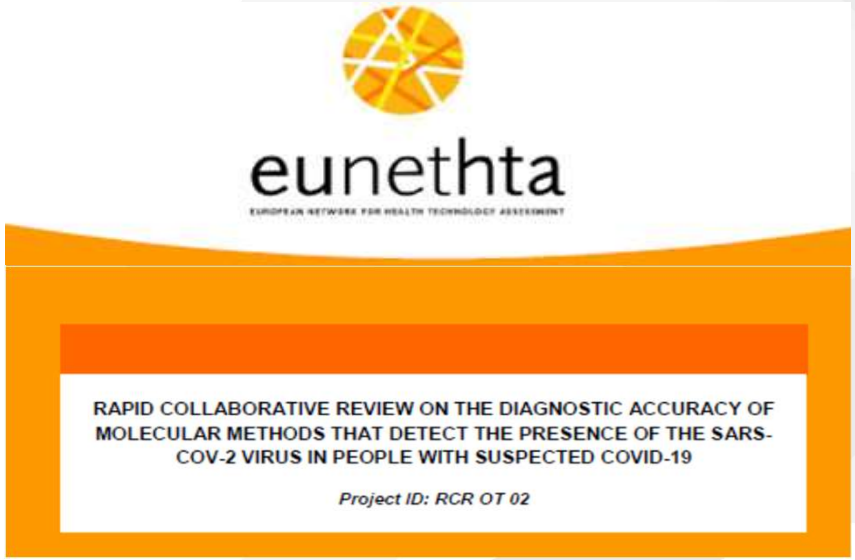


Hawlik, K., Rummel, P., Wild, C. (2018) Analysis of duplication and timing of health technology assessments on medical devices in Europe. Int J TAHC 34(1): 18-26.

2 Rapid REA on Antibody & Molecular tests



Published 22nd of June 2020



Published 4th of December 2020

23 Rolling Collaborative Reviews (RCR) of therapies

Project ID	Title	Version of RCR published	Author	Start of Procedure	Continuation
RCR01	Convalescent plasma therapy / CPT	9.0 – 20/04/21	HTW	August 2020	Yes, monthly
RCR02	Lopinavir + Ritonavir	4.0 – 23/11/20	NIPN	August 2020	No, stopped with November 2020
RCR03	Tocilizumab	9.0 – 20/04/21	NIPN	August 2020	Yes, monthly
RCR04	Camostat	8.0 – 20/04/21	KCE	August 2020	Yes, monthly
RCR05	Nafamostat	6.0 – 15/02/21	KCE	August 2020	Yes, monthly
RCR06	Solnatide	5.0 – 15/02/21	AIHTA	August 2020	Yes, bi-monthly
RCR07	Anakinra	9.0 – 20/04/21	AIHTA	August 2020	Yes, monthly
RCR08	Dexamethasone	2.0 – 15/09/20	AIHTA	August 2020	No, stopped with October 2020
RCR09	APN01	5.0 – 15/02/21	AEMPS, AETSA	August 2020	Yes, bi-monthly
RCR10	Darunavir	8.0 – 15/03/21	SNHTA	August 2020	Yes, monthly
RCR11	Favipiravir	9.0 – 20/04/21	SNHTA	August 2020	Yes, monthly
RCR12	Sarilumab	9.0 – 20/04/21	NIPH	August 2020	Yes, monthly
RCR13	Interferon and Novaferon	8.0 – 20/04/21	NIPH	September 2020	Yes, monthly
RCR14	Gimsilumab	2.0 – 15/09/20	SMCA	August 2020	Yes, bi-monthly
RCR15	Canakinumab	4.0 – 15/02/21	SMCA	August 2020	Yes, bi-monthly
RCR16	REGN-COV2 (Casirivimab + Imdevimab)	3.0 – 15/02/21	AIHTA	December 2020	No, stopped with February 2021
RCR17	Bamlanivimab (LY-CoV555)	3.0 – 15/02/21	AIHTA	December 2020	No, stopped with February 2021
RCR18	Baricitinib (LY3009104)	5.0 – 20/04/21	AIHTA	December 2020	Yes, monthly
RCR19	Molnupiravir (MK 4482/ EIDD-2801	5.0 – 20/04/21	AIHTA	December 2020	Yes, monthly
RCR20	High-dose vitamin D	2.0 – 15/03/21	GÖG	February 2021	Yes, monthly
RCR21	Mavrilimumab	3.0 – 20/04/21	SESCS	January 2021	Yes, monthly
RCR22	Ivermectin	3.0 – 20/04/21	AOTMiT	February 2021	Yes, monthly
RCR23	Aspirin	3.0 – 20/04/21	SNHTA	February 2021	Yes, monthly

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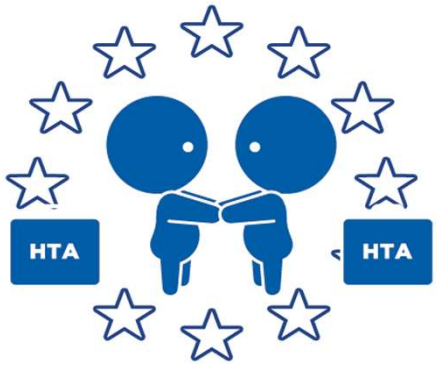

Conclusion

International (European) HTA collaboration is of utmost necessity for small countries to cover a wide range of technologies and to stay up-to-date in methodologies !

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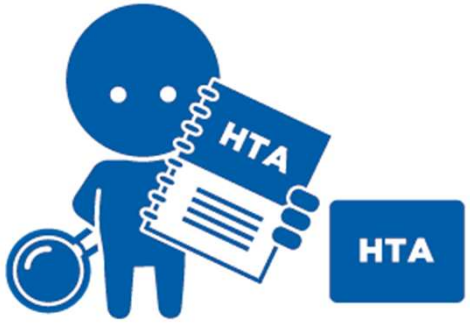
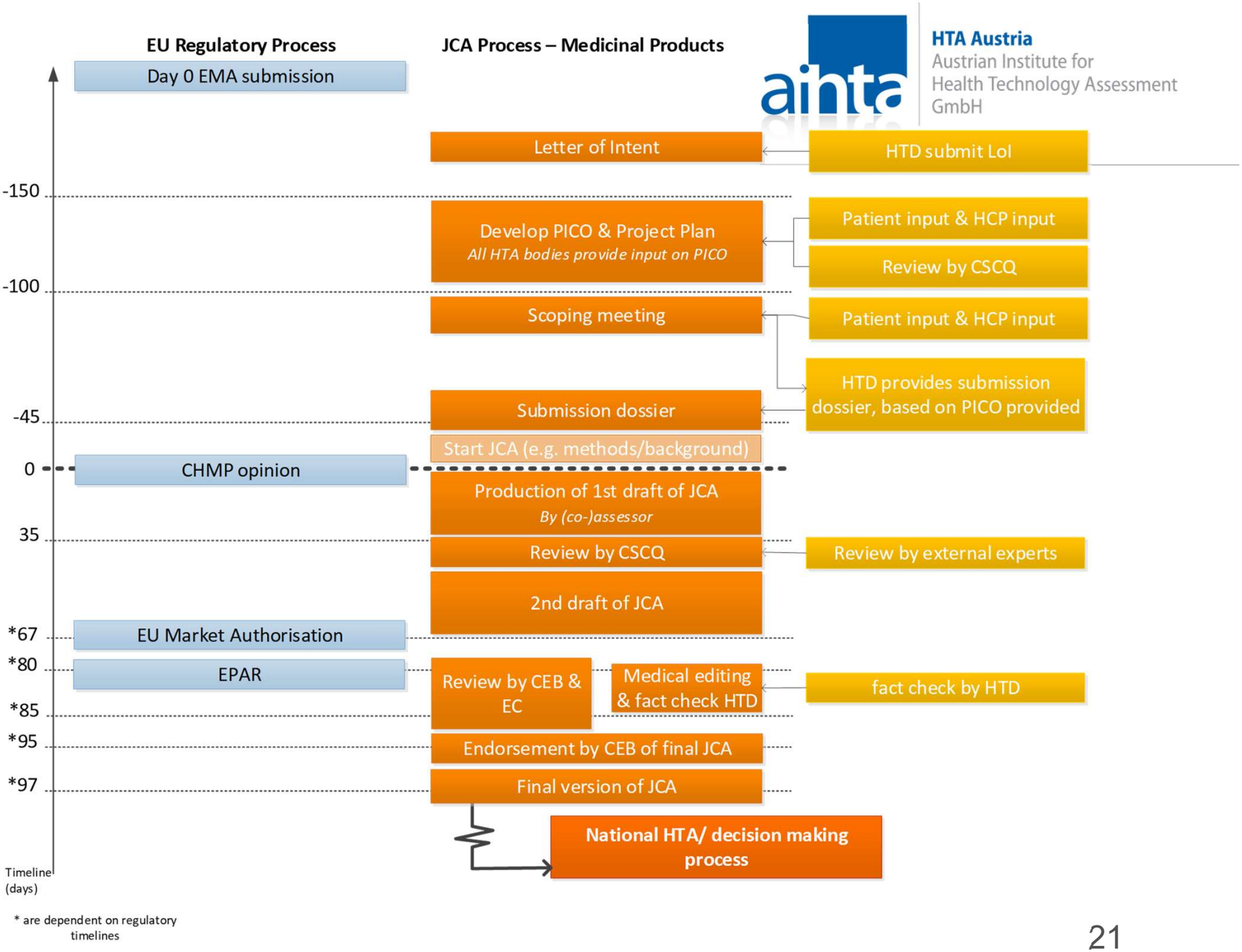
National AND international perspective




EU Regulatory Process
JCA Process – Medicinal Products
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Day 0 EMA submission
Letter of Intent
HTD submit LoI
-150
Develop PICO & Project Plan
All HTA bodies provide input on PICO
Patient input & HCP input
Review by CSCQ
-100
Scoping meeting
Patient input & HCP input
HTD provides submission dossier, based on PICO provided
-45
Submission dossier
Start JCA (e.g. methods/background)
0
CHMP opinion
Production of 1st draft of JCA
By (co-)assessor
35
Review by CSCQ
Review by external experts
2nd draft of JCA
*67
EU Market Authorisation
*80
EPAR
Review by CEB & EC
Medical editing & fact check HTD
fact check by HTD
*85
*95
Endorsement by CEB of final JCA
*97
Final version of JCA
National HTA/ decision making process
Timeline (days)
* are dependent on regulatory timelines

EUnetHTA: National Preparedness": Implementation concept for Austria

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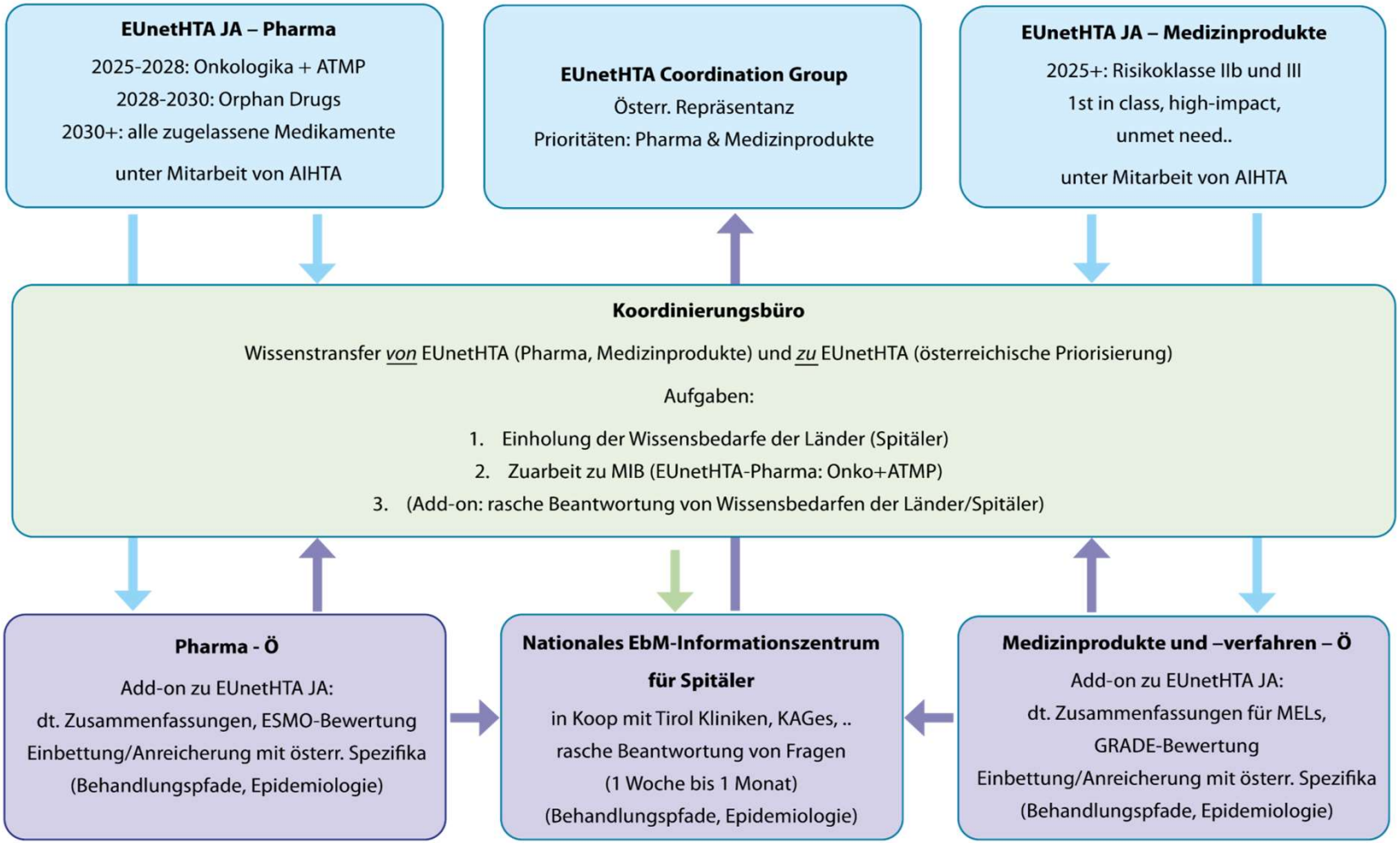

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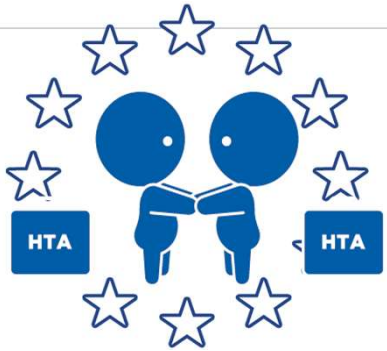
Conclusion



Implementation of the HTA R is challenging in decentralized countries: awareness of HTA R, coordination, flow of information, centralization of decsions (?) is needed.

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