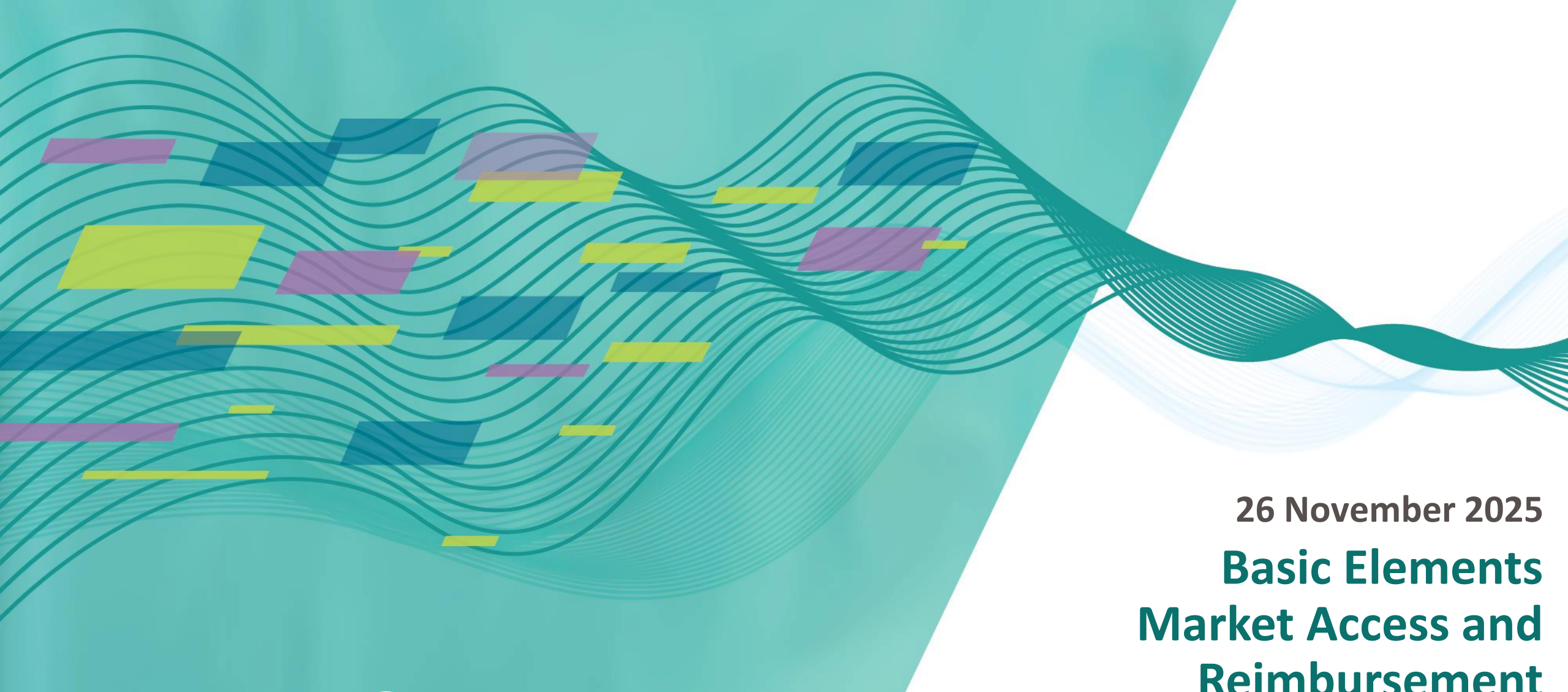


AVANIA

ADVANCING YOUR MEDICAL TECHNOLOGY

26 November 2025

Basic Elements Market Access and Reimbursement

Swiss Medtech

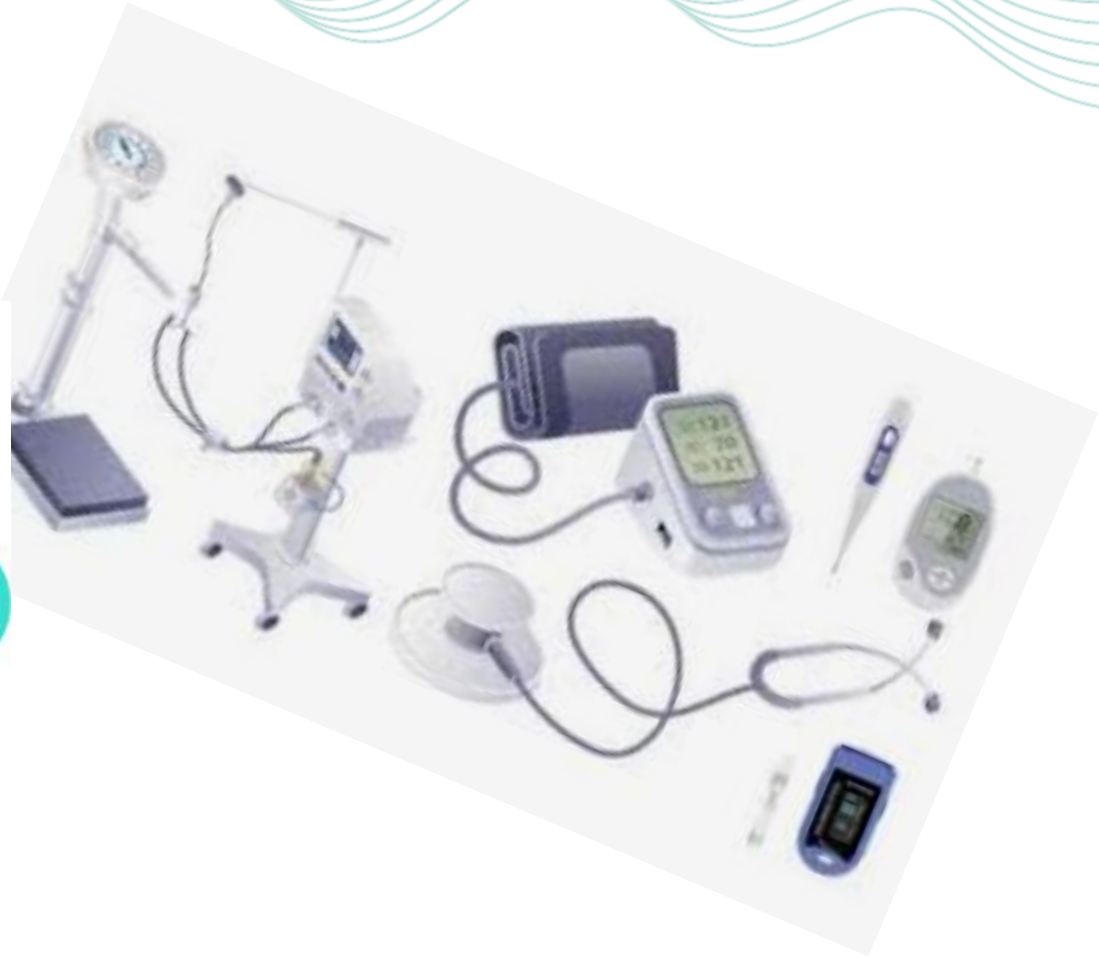
Meike Bomhof

Vice President

There is a big difference between obtaining regulatory approval and obtaining market access

Regulatory Approval ≠ **Market Access**

A long list of CE marked and FDA approved technologies **never** achieved market access!!



Let's understand the reasons!
Learnings you should have obtained at the end of this session

1. Understand why many CE marked technologies had a **difficulty to obtain market access and reimbursement**

2. The **key criteria used to prioritize the proposed markets of entry** for a technology.

3. Understand how market access and reimbursement parameters affect a **technology pricing strategy**

4. The importance of a clearly defined **value proposition** of your technology and the need for **clinical and health economic evidence** to back this up

5. Understand that the **time and resources required to obtain market access and optimal reimbursement will vary** significantly depending on the technology and market, and

In general, to gain an understanding of the meaning and relevance of the basic, universal, concepts of Medtech Market Access

AVANIA

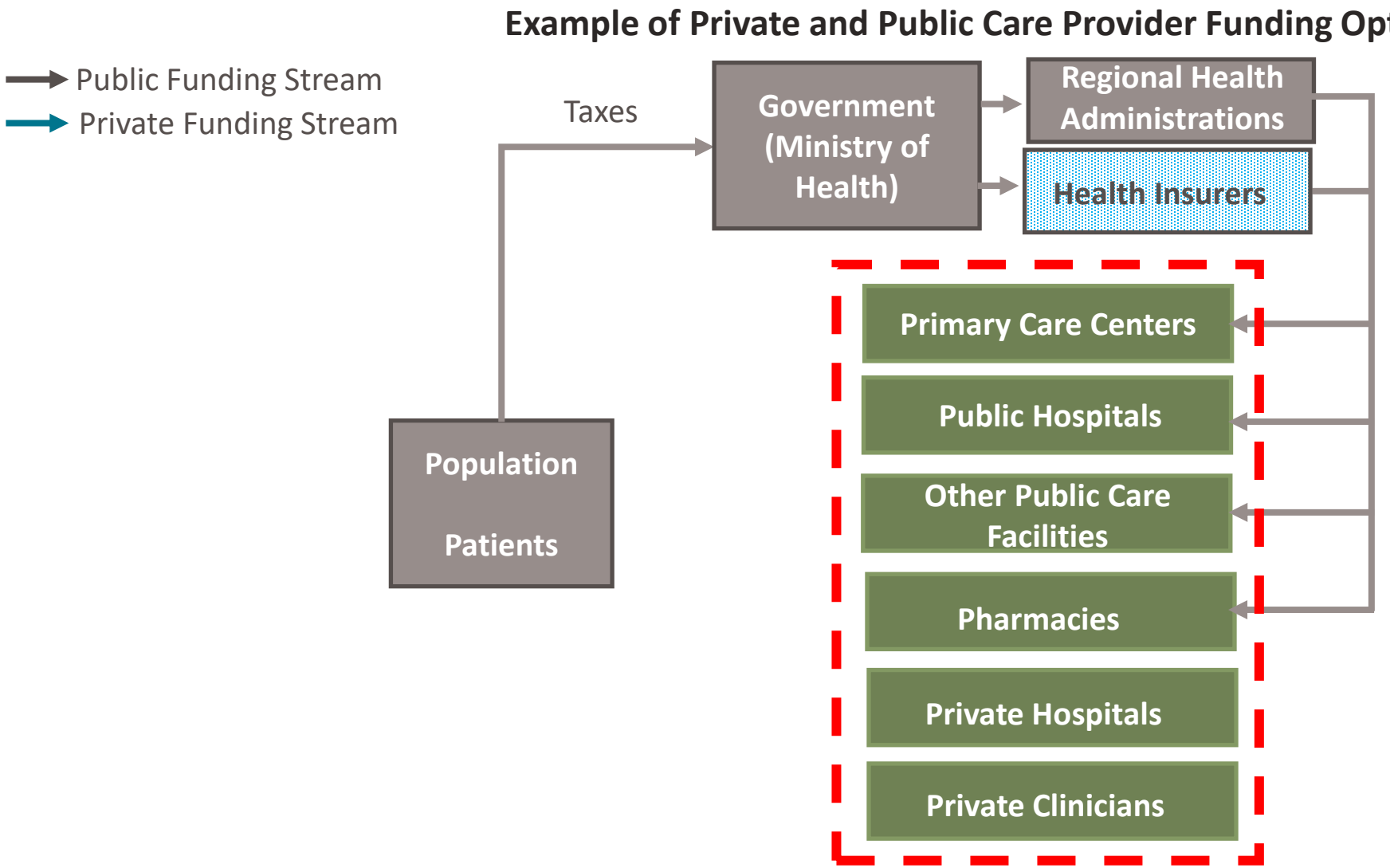
Contents

1. Role of Coding, Coverage and Payment on Market Access Strategy
2. Market Access Strategy Development
   - Timeline
   - Stakeholders & Value Proposition
3. Market Access Tools:
   - Clinical & Economic Evidence
   - Health Technology Assessments
   - Clinical guidelines

Section questions will provide you with the key areas of focus for a market access and reimbursement strategy

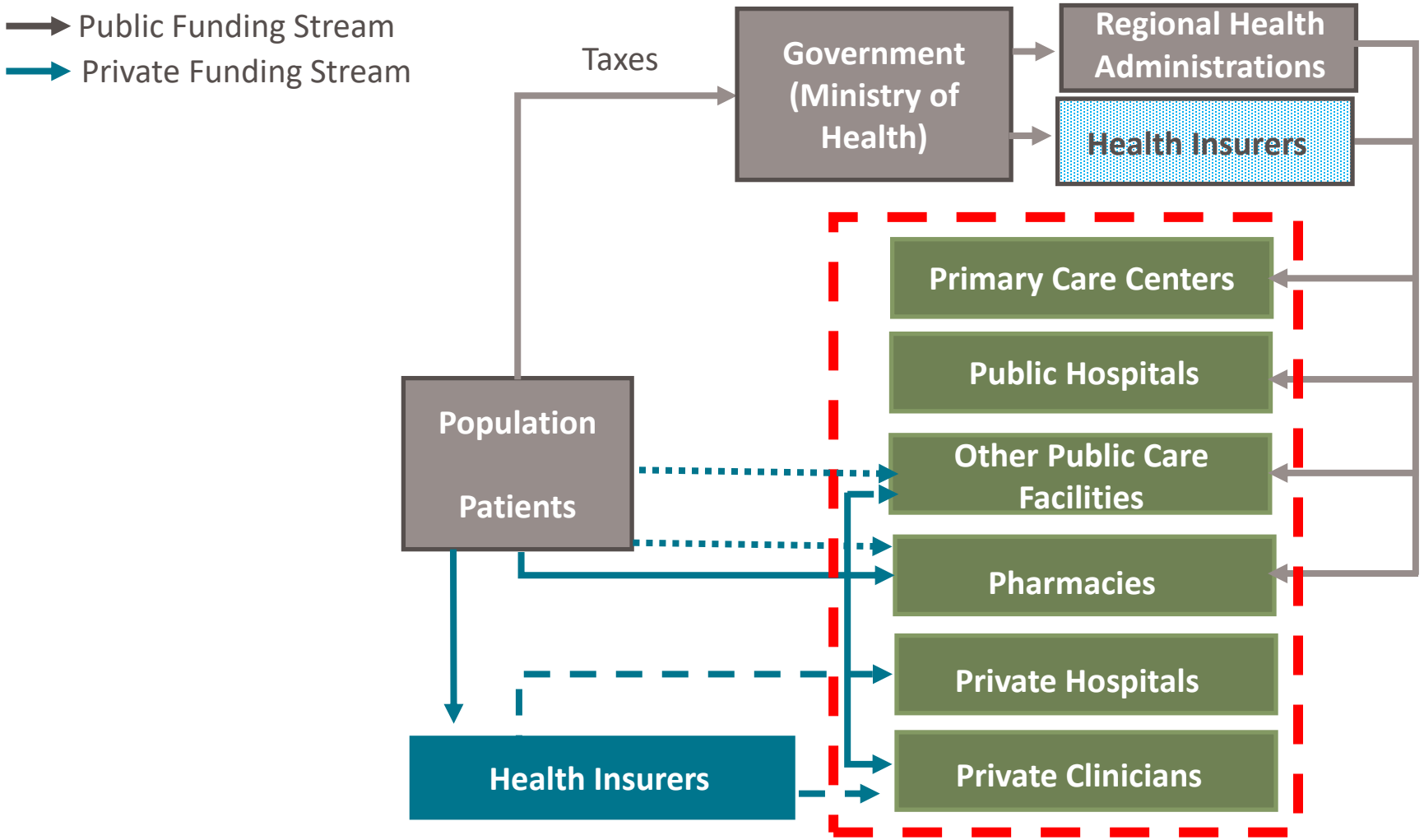
Background Healthcare Financing

In all markets the entities that will acquire your technologies are funded either by public payers, private payers or patients. These funds are used to acquire medical technologies

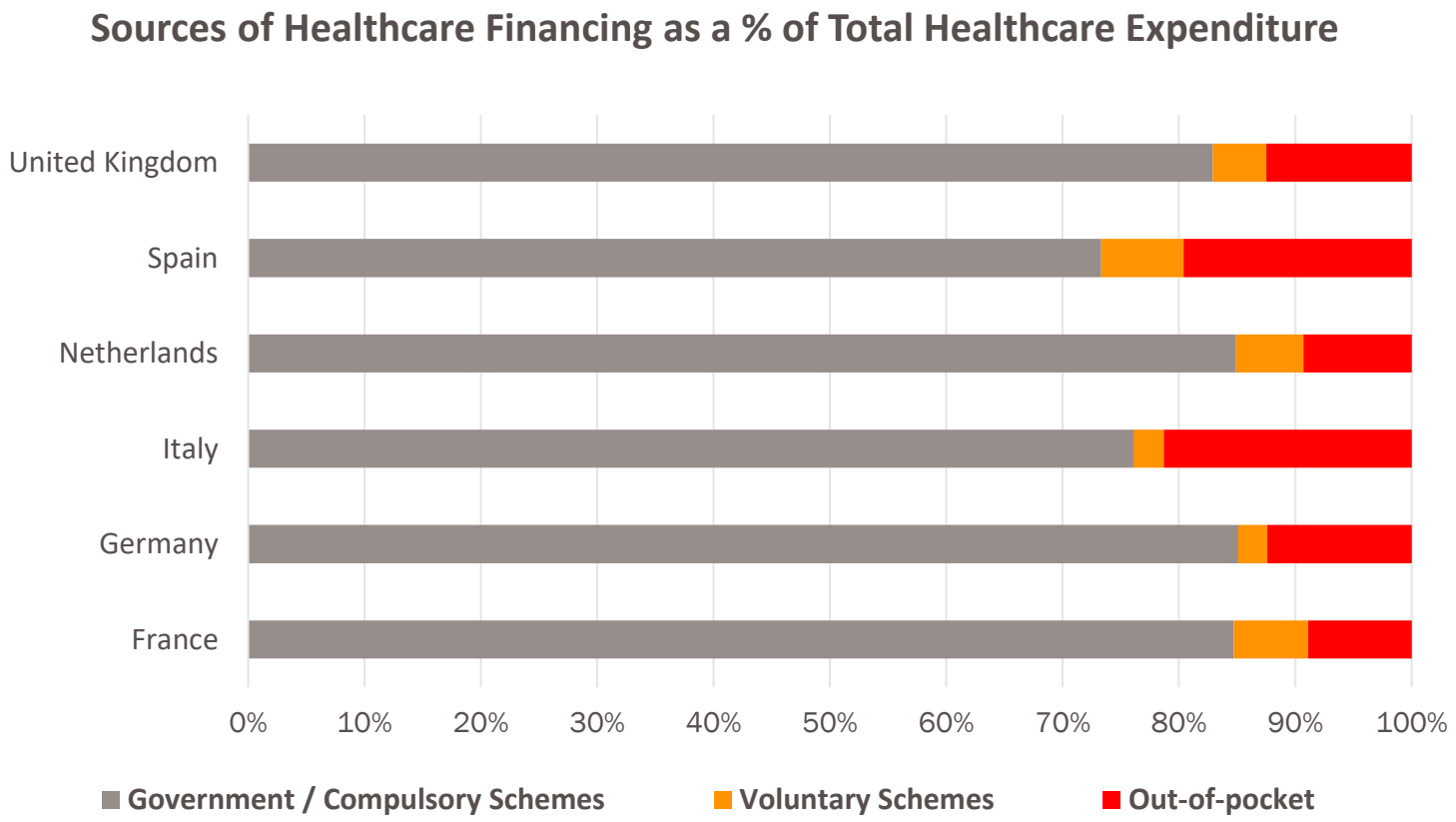


In all markets the entities that will acquire your technologies are funded either by public payers, private payers or patients. It is key to understand the funding pathways.

Example of Private and Public Care Provider Funding Options



Public sector healthcare funding maintains a dominant role in most EU markets. Some markets also present an opportunity for private sector funding.



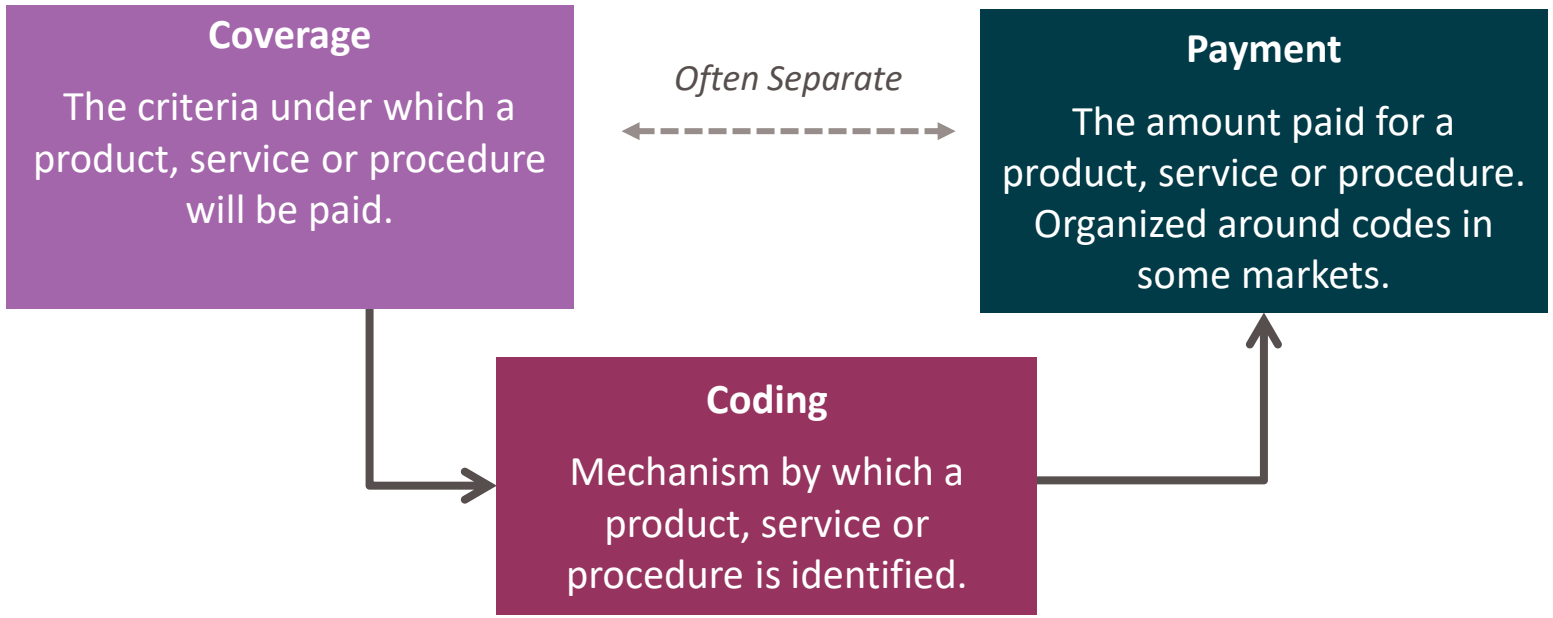
- Most EU countries rely on a mix of private and public funding.
- Public funding is used to cover “medically essential care”.
- Private funding is usually concentrated in certain elective areas.
  - Few countries rely heavily on private funding for medically essential care
- Markets are characterized by stable or reduced healthcare expenditure

Role of Coding, Coverage and Payment on Market Access Strategy

AVANIA

Market Access and Reimbursement consist of 3 core elements: Coverage, Coding and Payment

Core Elements of Market Access and Reimbursement: Coverage, Coding, and Payment



- Separate but related processes and requirements
- Very few countries decide all three factors under a single process or by a single agency.
- Market Access of innovative technologies can fail due to any one of these elements.

Step 1:
Understand the impact of these elements on your particular technology in each market

Coverage

Coverage: Most countries define a basket of basic healthcare services for coverage from public funds

Spain public sector coverage

Contenido de la Cartera de servicios

- Prestaciones de salud pública
- Atención primaria.
- Atención especializada.
- Atención de urgencia.
- Prestación farmacéutica.
- Prestación ortoprotésica (implantes quirúrgicos, prótesis externas, ortesis, sillas de ruedas y ortoprótesis especiales).
- Prestación de productos dietéticos (dietoterápicos complejos y nutrición enteral domiciliaria)
- Prestación de transporte sanitario.

Spain private sector coverage

DKV Adeslas MAPFRE Sanitas

- Private insurance companies offer health insurance covering a predefined basket of services

- Spain: “Common Services Portfolio” contains all healthcare services covered with public funds for Spanish citizens
- Regions are allowed to cover additional health services through regional portfolios
- Cosmetic surgery / Dental care are not “covered”!

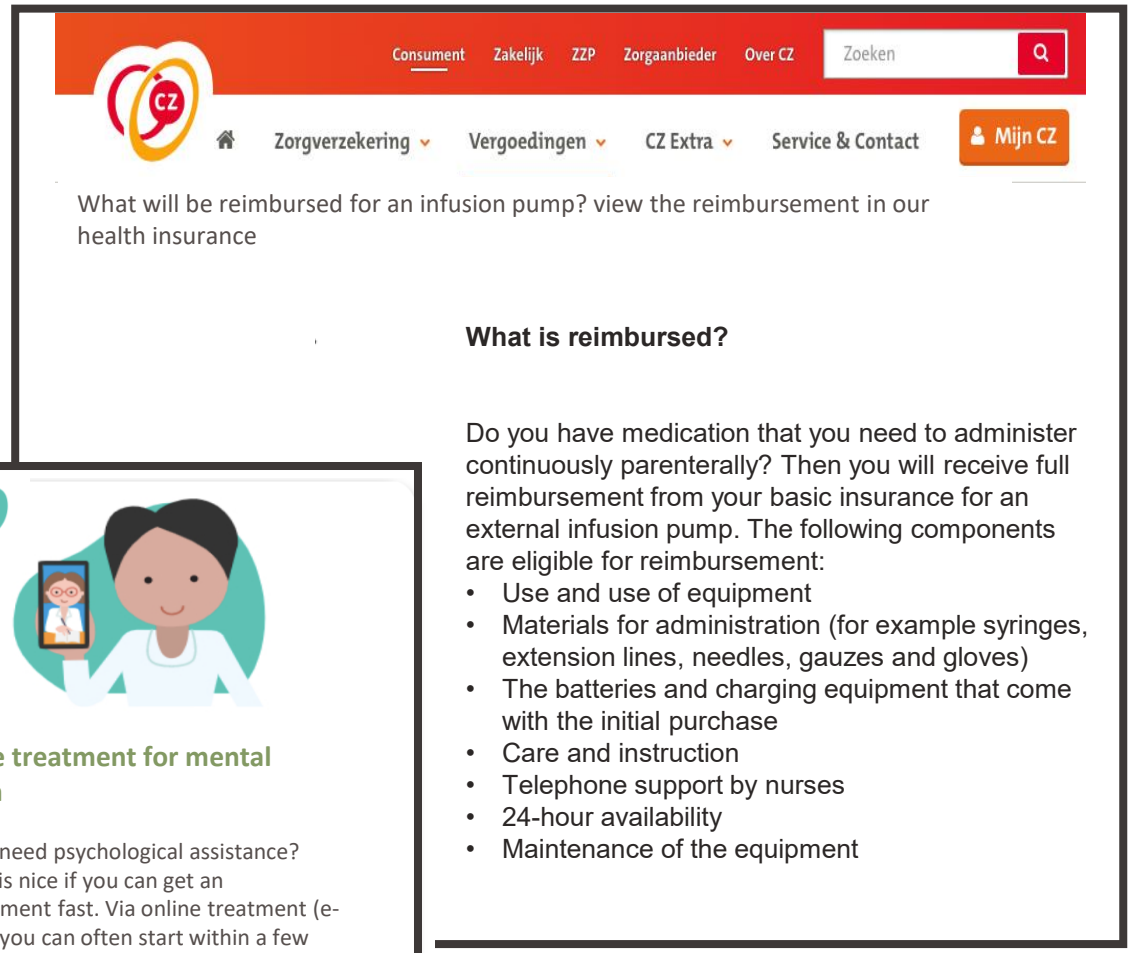
AVANIA

Coverage: In some markets, regions are free to cover health services in addition to a national basket

Italy public sector coverage

- Italy: LEA “Essential Levels of Assistance”
- Example: “Intra Ocular Lens” (IOL): Cataract surgery is covered by the LEA. Refractive errors are not, but hospitals in some regions may charge patients a co-payment for refractive IOL’s

Coverage: In some markets private insurance companies co-define public healthcare coverage



The Netherlands Public Sector Coverage

- Insurance companies cover mandatory Basic Basket of Healthcare Services approved by the Ministry of Health
- In addition, insurance companies are free to offer supplementary services through supplementary voluntary insurance packages

Coverage of medical technologies is often subject to limitations

ZA-omschrijving	Uitleg
Cochlear implants (pre) implant in children	Bilateral cochlear implantation in children only complies with current scientific knowledge and practice and is therefore only **covered for bilaterally deaf and profoundly hearing-impaired children up to the age of 5** (2012 position). Insured individuals aged 5 to 18 may be eligible for a second cochlear implant **provided they meet the indication criteria of the CION guideline** (2014 position).
Cochlear implant after-care in children	
Replacement cochlear implant processor in children	

Question; Is your technology covered in the market of interest in the public and / or private setting and at national and/or regional level?

- Public coverage decisions are taken at national - and regional – level, depending on the market
- Decisions are usually taken based on prioritization process of requests **AND for political reasons**

PrTec Prioritization Model Eligibility Criteria	Weight
Pathology (severity, frequency, unmet need, vulnerability)	**33**
Comparative results (safety/effectiveness)	**25.5**
Economic impact (direct and indirect costs)	**20.5**
Implications of implantation (organizational, budget impact, ethical, social, legal	**10.5**
Dissemination (health / efficiency benefits; social, political or professional demand / interest)	**10.5**

In Switzerland, the criteria to obtain coverage for novel technologies rely on proven effectiveness, appropriateness and economic efficiency

- To achieve coverage and reimbursement in Switzerland, an assessment will be conducted (by the BAG) of new technologies seeking higher reimbursement through a GRADE evaluation.

Assessment Objectives

Technology is Effective	Technology is Appropriate	Technology is Economical
• Objectively suitable in achieving therapeutic benefit • Proven favorable ratio of benefit and harm compared to alternative therapies • Study parameters align with established Swiss clinical practice	• Relevant and suitable for patients compared to alternative procedures, • Compatible with the legal conditions, ethical and social aspects or values and • Appropriate application in practice are guaranteed	• Comparable tariffs / cost • Favorable cost-benefit ratio compared to the alternative • Cost implications for compulsory health insurance are acceptable

Coverage: Questions to ask yourself for each market

The first step of a market access strategy requires defining the coverage limitations applicable to your technology <u>in each target market</u>

1. **Coverage**: Is your procedure or device "covered" in the target market
   - In the public and / or private setting?
   - At national and /or regional level?
   - In the applicable setting of care (inpatient, outpatient, other)?
   - For the relevant indication / subset of patients?
   - What, if any, coverage limitations exist?

Coding

Coding: In most countries coding is determined by setting of care and technology type.

Setting of Care

- Inpatient
- Outpatient
- Homecare

Type of Technology

- Consumables
- Implantables
- Capital Equipment
- Technical Aids
- Software (as a service)
- eHealth
- Other?

- To understand which coding system applies we need to identify **where** your technology is used and **the technology type.**

AVANIA

Coding for outpatient procedures
Outpatient procedures are usually coded in ambulatory care Fee Schedules

Netherlands Hospital Outpatient Fee Schedule

Passantenprijslijst 2025 - UMC Utrecht

Versie	1-jan-25
Ingangsdatum:	1 januari 2025
Einddatum:	31 december 2025

UMC Utrecht

Zorgproduct	Declaratiecode	ZorgproductOmschrijving
OVPXXXXXX	039507	Begeleiding en interpretatie farmacologische stress-test door cardioloog bij MRI-hart inclusief voor- en nabespreking met radioloog.
OVPXXXXXX	039601	Onderzoek gevoeligheid allergenen dmv huidtest(s), met huidpriktests of intracutane injecties, per zitting.
OVPXXXXXX	039611	Extra Corporele Membraan Oxygenatie (ECMO) incl. toeslag bij behandeling op Neonatale IC of Pediatrische IC (zie 039610 voor ECMO bij behandeling van volwassenen).
OVPXXXXXX	039665	Standaard intra-operatieve neuromonitoring.
OVPXXXXXX	039666	Langdurige intra-operatieve neuromonitoring.
OVPXXXXXX	039667	Zeer langdurige intra-operatieve neuromonitoring.
OVPXXXXXX	039688	Uitgebreide kwantitatieve analyse electromyografisch (EMG).
OVPXXXXXX	039702	Standaard electro-encephalografie (EEG), registratie tot 1 uur.
OVPXXXXXX	039705	Langdurige electro-encephalografie (EEG), registratie vanaf 6 tot 24 uur.
OVPXXXXXX	039708	AMBULANTE 24-UURS ELECTRO-ENCEPHALOGRAFIE (EEG)-REGISTRATIE.
OVPXXXXXX	039709	Electro-encephalografie (EEG) bij hersendoodprocedure.
OVPXXXXXX	039712	24-UURS ELECTRO-ENCEPHALOGRAFIE (EEG)-REGISTRATIE MET DIEPTE ELEKTR.
OVPXXXXXX	039715	Aanvullende eenvoudige kwantitatieve analyse electro-encephalografie (EEG).
OVPXXXXXX	039716	Aanvullende uitgebreide kwantitatieve analyse electro-encephalografie (EEG).
OVPXXXXXX	039717	Aanvullende videoregistratie (tijdens EEG tot 1 uur).
OVPXXXXXX	039718	Aanvullende videoregistratie tijdens EEG-registratie 1-2 uur, 2-6 uur of 6-24 uur.
OVPXXXXXX	039722	ELECTRO-OCULOGRAFIE (EOG).
OVPXXXXXX	039729	Slaap-Apneu registratie (screening).

AVANIA

Coding for outpatient procedures
Outpatient procedures are usually coded in ambulatory care Fee Schedules

Bundesamt für Gesundheit BAG

Krankenpflege-Leistungsverordnung KLV, Anhang 1*a*

Anhang 1a der Krankenpflege-Leistungsverordnung (KLV)

Der Anhang 1*a* der KLV enthält die Liste der nach Artikel 3*c* KLV grundsätzlich ambulant durchzuführenden Eingriffe und die Kriterien zugunsten einer stationären Durchführung und definiert die Kostenübernahme.

Ausgabe vom 1. Januar 2025

I. Liste der grundsätzlich ambulant durchzuführenden elektiven Eingriffe

1. Augen

1.1 Katarakt (grauer Star)

Kode gemäss CHOP Version 2025[5]	Bezeichnung
13.11	Intrakapsuläre Extraktion der Linse durch inferioren temporalen Zugang
13.19	Intrakapsuläre Extraktion der Linse, sonstige
13.2	Extrakapsuläre Extraktion der Linse durch lineares Extraktionsverfahren
13.3	Extrakapsuläre Extraktion der Linse durch einfaches Aspirations- (und Irrigations-) Verfahren
13.41	Phakoemulsifikation und Aspiration eines Katarakts
13.42	Mechanische Phakofragmentation und Aspiration eines Katarakts durch posterioren Zugang
13.43	Mechanische Phakofragmentation und andere Aspiration eines Katarakts
13.51	Extrakapsuläre Extraktion der Linse durch inferioren temporalen Zugang
13.59	Sonstige extrakapsuläre Extraktion der Linse, sonstige
13.64	Diszision einer Sekundärmembran (nach Katarakt)
13.65	Exzision einer Sekundärmembran (nach Katarakt)
13.66	Mechanische Fragmentation einer Sekundärmembran (nach Katarakt)
13.69	Sonstige Kataraktextraktion, sonstige

Coding for outpatient procedures
Outpatient procedures are usually coded in ambulatory care Fee Schedules

Coding for Outpatient Procedures - Basque Country Diagnostics Fee Schedule

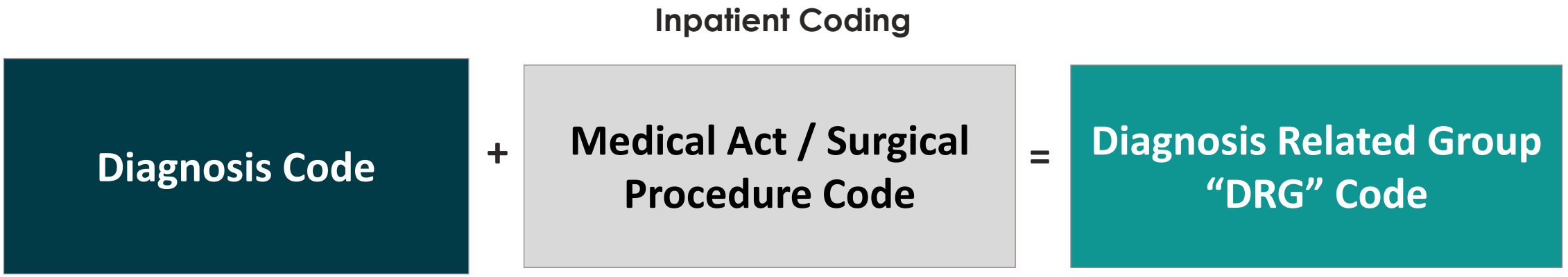
A.10.I) NEUROFISIOLOGÍA

Prestación	Artículo
E.E.G. Simples	10001519
Electromiograma. Guía toxina botulínica.	10001521
Potencial Evocado (unitario). Miogénico/PEAT/PES/PEV	10001522
PEAT menor de 5 años	10018106
Multitest Potencial Evocado	10001523
EEG con privación de sueño	10003641
Blink-réflex	10018107
Enf. Motoneurona	10018108
Estimulación Repetitiva	10018109
Jitter	10018110
ERG	10018111
Estimulación Magnética	10018112

Osakidetza

ZUZENDARITZA NAGUSIA
DIRECCIÓN GENERAL

Coding for inpatient procedures
Inpatient procedures are subject to three different codes



Coding for inpatient procedures
Procedures to treat a particular diagnosis map to a DRG

Procedure coding, DRG mapping, and Tariffs for Benchmark Bariatric Surgical Procedures

Diagnosis Code: ICD9 Disease Classification **278.XX** "Obesity"

Technology	Procedure Code	DRG Code
Gastric Balloon	44.93 Insertion of gastric balloon	**288** procedures for obesity
Gastric banding	44.95 Laparoscopic gastric restrictive procedure	
Vertical banded gastroplasty	44.68 Laparoscopic Gastroplasty	
Gastric Bypass	44.31 High gastric bypass	
Biliopancreatic Diversion (BPD)*	Main: 43.7 Partial gastrectomy with anastomosis to jejunum Other: 45.91 Small-to-small intestinal anastomosis	
Gastric Sleeve*	Main: 43.89 Other partial gastrectomy Other: 44.99 Other operations on the stomach	

AVANIA

Coding for inpatient procedures
Different technologies used to treat the same indication can also map to different DRG's

Example Procedure Coding and DRG Mapping for Ablation Treatment for Liver Cancer

*ICD9 Disease Classification **155.XX** "Malignant neoplasm of liver and intrahepatic bile ducts"*

Procedure Type	Procedure Code and Description	DRG Code and Description
Microwave ablation Cryotherapy	**99.85** Hyperthermia for treatment of cancer, induced by microwave, ultrasound, low energy radio frequency, probes **+ 38.19** Arterial catheterization	**203** Malignancy of hepatobiliary system or pancreas
Radiofrequency ablation	**50.29** Other destruction of lesion of liver (cauterization, enucleation or evacuation of hepatic lesion) **+ 50.25** laparoscopic ablation of liver lesion or tissue	**191** Pancreas, liver and shunt procedures with complications
Surgery	**50.22** Partial hepatectomy / 50.23 Open ablation of liver lesion or tissue / 50.30 Lobectomy of liver / 50.40 Total hepatectomy	**192** Pancreas, liver and shunt procedures without complications
Other	**50.24** Percutaneous ablation of liver lesion or tissue	

AVANIA

Prosthesis coding includes surgical implants, external prostheses & orthesis.

Spain Orthoprosthesis Nomenclator

BOLETÍN OFICIAL DEL ESTADO
Núm. 162 Miércoles 8 de julio de 2015 Sec. I. Pág. 56623

VA 1 Implantes endovasculares (conforme a los protocolos de cada administración sanitaria competente).

VA 1 0 Endovascular cerebral.

V A 1 0 1 Stent convencional.

V A 1 0 1 0 Autoexpandible.
V A 1 0 1 1 Expandible con balón

V A 1 0 2 Stent derivador de flujo.

VA 1 1 Endovascular coronario.

VA 1 1 0 Stent no impregnado.

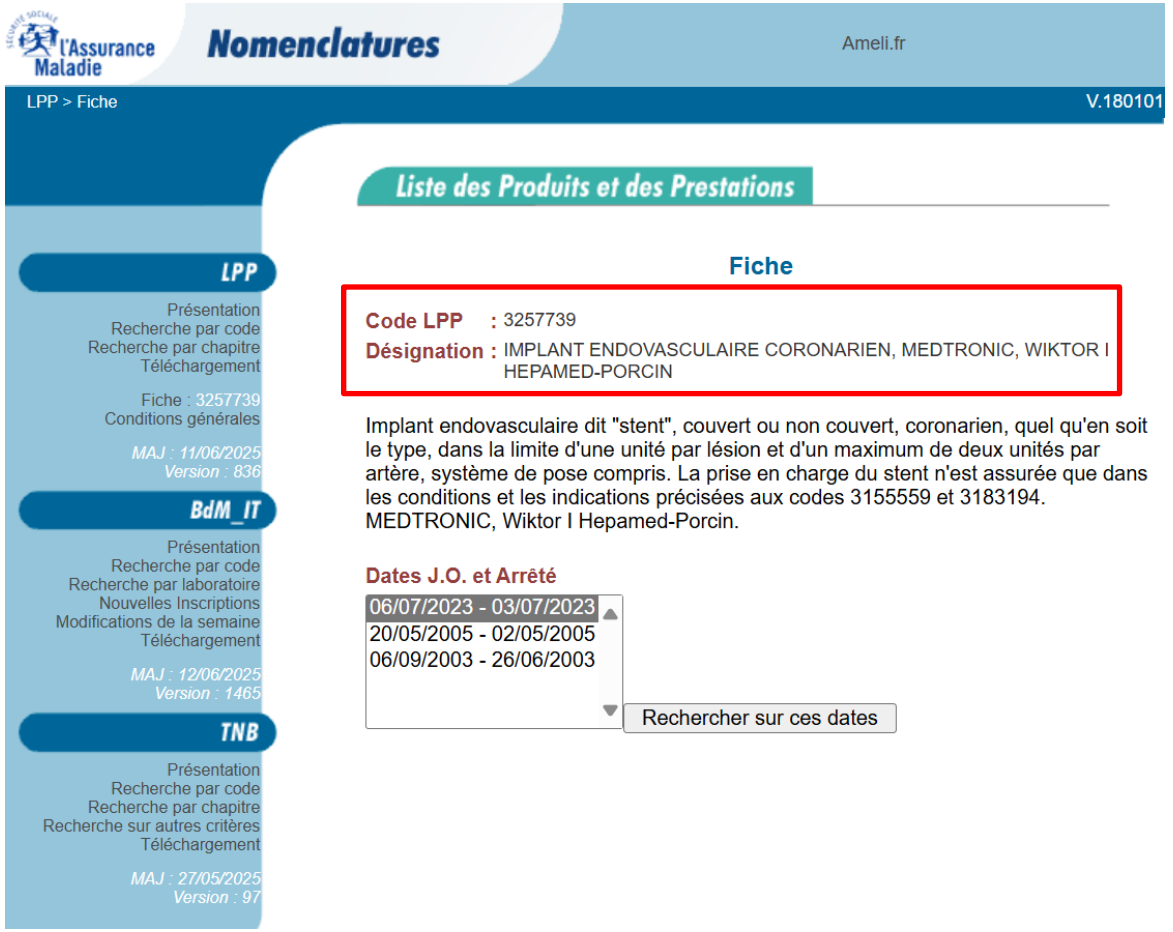
VA 1 1 0 0 Simple.
VA 1 1 0 1 Bifurcado.

VA 1 1 1 Stent impregnado.

VA 1 1 1 0 Con fármaco antiproliferativo.

VA 1 1 1 0 0 Simple.
VA 1 1 1 0 1 Bifurcado.
VA 1 1 1 1 Con fármaco no antiproliferativo.
VA 1 1 2 Stent biorreabsorbible, para tratamiento de la cardiopatía isquémica en pacientes con lesiones coronarias de novo en arteria coronaria nativa y enfermedad de uno o dos vasos, fuera de la fase aguda del infarto de miocardio, sin contraindicación relativa a la doble terapia antiagregante y con ausencia de afectación de tronco coronario o by-pass aorto-coronario.

Prosthesis Coding
Implantable prosthesis coding is country specific



Medical Aids coding
Local coding also applies to medical aids

Italy Prosthesis Nomenclator (by function)

ELENCO N. 2:
Tavola di corrispondenza fra sistemi di classificazione

FAMIGLIE DI AUSILI SECONDO IL NOMENCLATORE TARIFFARIO EX D.M. 28/12/92	CLASSI DI AUSILI CORRISPONDENTI SECONDO LA CLASSIFICAZIONE A NORMA ISO
22 - AUSILI PER LA STABILIZZAZIONE, POSTURA E DEAMBULAZIONE	**12 AUSILI PER LA MOBILITA' PERSONALE** 12.9 Ausili per deambulazione (stampelle, tripodi, quadripodi, deambulatori) 12.10 Biciclette (a due ruote) 12.21 Carrozzine (a telaio rigido, ad autospinta unilaterale, motocar-rozzine) **12.27.3** Passeggini (tipo chiudibile ad ombrello) **12.36** Sollevapersone 18.09 Seggiolone normale
101 AUSILI PER L'INCONTINENZA	**09 AUSILI PER LA CURA E LA PROTEZIONE PERSONALE** 09.12 ausili per evacuazione 09.18 ausili per stomia 09.27 raccoglitori per urina 09.24 cateteri esterni e vescicali 09.30 ausili assorbenti l'urina **18 FORNITURE ED ADATTAMENTI PER LA CASA** 18.12 letti (traverse assorbenti)
201 AUSILI PER LA FUNZIONE VISIVA	**09 AUSILI PER LA CURA E LA PROTEZIONE PERSONALE** 09.51 orologi 09.48 ausili per la misurazione della temperatura corporea **12 AUSILI PER LA MOBILITA' PERSONALE** 12.03 ausili per la deambulazione (bastoni per non vedenti) **21 AUSILI PER LA COMUNICAZIONE E L'INFORMAZIONE** 21.06 ausili ottici elettronici 21.15 ausili per la scrittura

AUSILI PER LA TERAPIA DELL'ERNIA
(AUSILI ADDOMINALI)

DESCRIZIONE	CODICE EX D.M. 28/12/92	CODICE CLASSIFICA-ZIONE ISO
L'applicazione e la fornitura di questi ausili è fatta dal tecnico ortopedico abilitato.		
VENTRIERE COSTRUITE SU MISURA		
Post - operatoria (appendicectomia, erniotomia) alta cm. 18	28.01.001	03.12.06.003
Per ptosi viscerale (gastrica, renale) con cuscinetto sottocoscia alta fino a cm. 30	28.01.003	03.12.06.006
Per sventramento semplice o per ptosi o per diastasi dei retti	28.01.005	03.12.06.009
Per sventramento addome pendulo, con tirante sovrapubico ed eventuali bretelle, su misura:		
- per uomo o donna fino a cm. 120	28.01.009	03.12.06.012
- per uomo o donna oltre cm. 120	28.01.011	03.12.06.015
CINTI ERNIARI SU MISURA PER ADULTI		
Possono essere forniti esclusivamente ad invalidi non operabili.		
Inguinale semplice o crurale		
- in tessuto elastico	28.05.001	03.12.06.033
- a molla	28.05.003	03.12.06.036
Inguinale doppio:		
- in tessuto elastico	28.05.005	03.12.06.039
- a molla	28.05.007	03.12.06.042
Scrotale per ernia incontenibile e sospensorio:		
- normale	28.05.013	03.12.06.045
- per ernia voluminosa	28.05.015	03.12.06.048
AGGIUNTIVI		
Foro per stomia su ventriera	---	03.12.06.103

Medical Aids coding
Single use medical aids are subject to local coding, and coverage limitations

Italy Single Use Medical Aids Nomenclator

AUSILI MONOUSO

I dispositivi medici elencati devono essere conformi al d. lgs. 24 febbraio 1997, n. 46 in attuazione della direttiva 93/42/CEE

Classe 09 "Ausili per la cura e la protezione personale"

09.18 ausili per stomia

09.18.04 sacche per stomia, a un pezzo, a fondo chiuso

dispositivi dotati di filtro antiodore, barriera protettiva autoportante in idrocolloidi o anello protettivo (in gomma naturale Karaya o diverso materiale), supporto adesivo microporoso e ipoallergenico; sul lato-corpo, rivestimento antitraspirante (in TNT o analogo materiale) e sul lato esposto, rivestimento in materiale opaco o trasparente.

09.18.04.003 **sacca per colostomia a fondo chiuso**

09.18.04.006 **sacca per colostomia a fondo chiuso per stomi introflessi (stoma a filo, retratto, situato in una piega cutanea o in una cicatrice)**

NOTA - Le quantità massime erogabili sono da intendersi per ogni stomia e sono incrementabili, a giudizio dello specialista prescrittore, fino al 50% nel periodo iniziale di assistenza ed addestramento all'uso di durata non superiore a 6 mesi.

09.18.05 sacche per stomia, a più pezzi, a fondo chiuso

09.18.05.003 **sistema per colostomia (placca adesiva con flangia + sacche a fondo chiuso)**

09.18.05.006 **sistema per colostomia (placca adesiva con flangia a convessità integrale per stomi introflessi (stoma a filo, retratto o situato in una**

NOTA - Le quantità massime erogabili sono da intendersi per ogni stomia e sono incrementabili, a giudizio dello specialista prescrittore, fino al 50% nel periodo iniziale di assistenza ed addestramento all'uso di durata non superiore a 6 mesi.

09.18.07 sacche per stomia, a un pezzo, a fondo aperto con valvola anti-reflusso

La sacca per ileostomia deve essere dotata di filtro antiodore, barriera autoportante in idrocolloidi o anello protettivo (in gomma naturale Karaya o diverso materiale), supporto adesivo microporoso e ipoallergenico, rivestimento antitraspirante (in TNT o analogo materiale) sul lato corpo e rivestimento opaco o trasparente sul lato esposto, valvola anti-reflusso. ***La sacca per urostomia*** deve essere dotata di un sistema di scarico (preferenzialmente con rubinetto a scomparsa) raccordabile al raccoglitore da gamba o da letto, con o senza cintura di fissaggio. ***Per entrambe***, il sistema di svuotamento e di chiusura della sacca deve essere facile da usare, sicuro ed efficace nel prevenire eventuali fuoriuscite.

Coverage Limitations

The maximum quantities that can be dispensed are intended for each stoma and can be increased at the discretion of the prescribing specialist, up to 50% in the initial period of assistance and training in use, not exceeding 6 months.

All diagnosis and medical acts are coded but different coding systems are used depending on country and setting of care. What setting of care and coding system applies to your technology?

Country	Setting	Diagnosis Coding	Procedure Coding
Germany	Inpatient	ICD-10-GM Diagnosis Codes, German Modification	OPS (Operation and Procedure Coding System, Operationen- und ProzedurenSchlüssel
	Outpatient	ICD-10-GM Diagnosis Codes, German Modification	EBM: Uniform Value Scale Einheitlicher Bemessungsmassstab
France	Inpatient	ICD-10 Diagnosis Codes	CCAM: Common Classification onf Medical Acts Classification Commune des Actes Médicaux
	Outpatient	ICD-10 Diagnosis Codes	CCAM coding
UK	All Settings (Public Hospitals)	ICD-10 Diagnosis Codes	OPCS: Office for Population Censuses and Surveys Classification
Italy	Inpatient	ICD-9 Diagnosis Codes	ICD-9 Procedure Codes
	Outpatient	ICD-9 Diagnosis Codes	Local NTPA: Nomenclatore Tariffario delle Prestazioni Ambulatoriali
Spain	Inpatient	ICD-9 Diagnosis Codes	ICD-10 CM Procedure Codes
	Outpatient	ICD-9 Diagnosis Codes	Local coding

- Some countries also code medical devices used as part of a procedure
- Capital equipment is not coded
- Implantable / Ortho-prosthesis device coding is country specific

Coding: Questions to ask yourself for each market

The second step of a market access strategy requires defining the coding system applicable to your technology <u>in each target market</u>

1. In which **setting of care** will your product be provided: inpatient / outpatient / homecare / other?

2. **Coding:** Does existing coding describe your technology adequately?

    I. Inpatient: Does an existing procedure code describe your technology

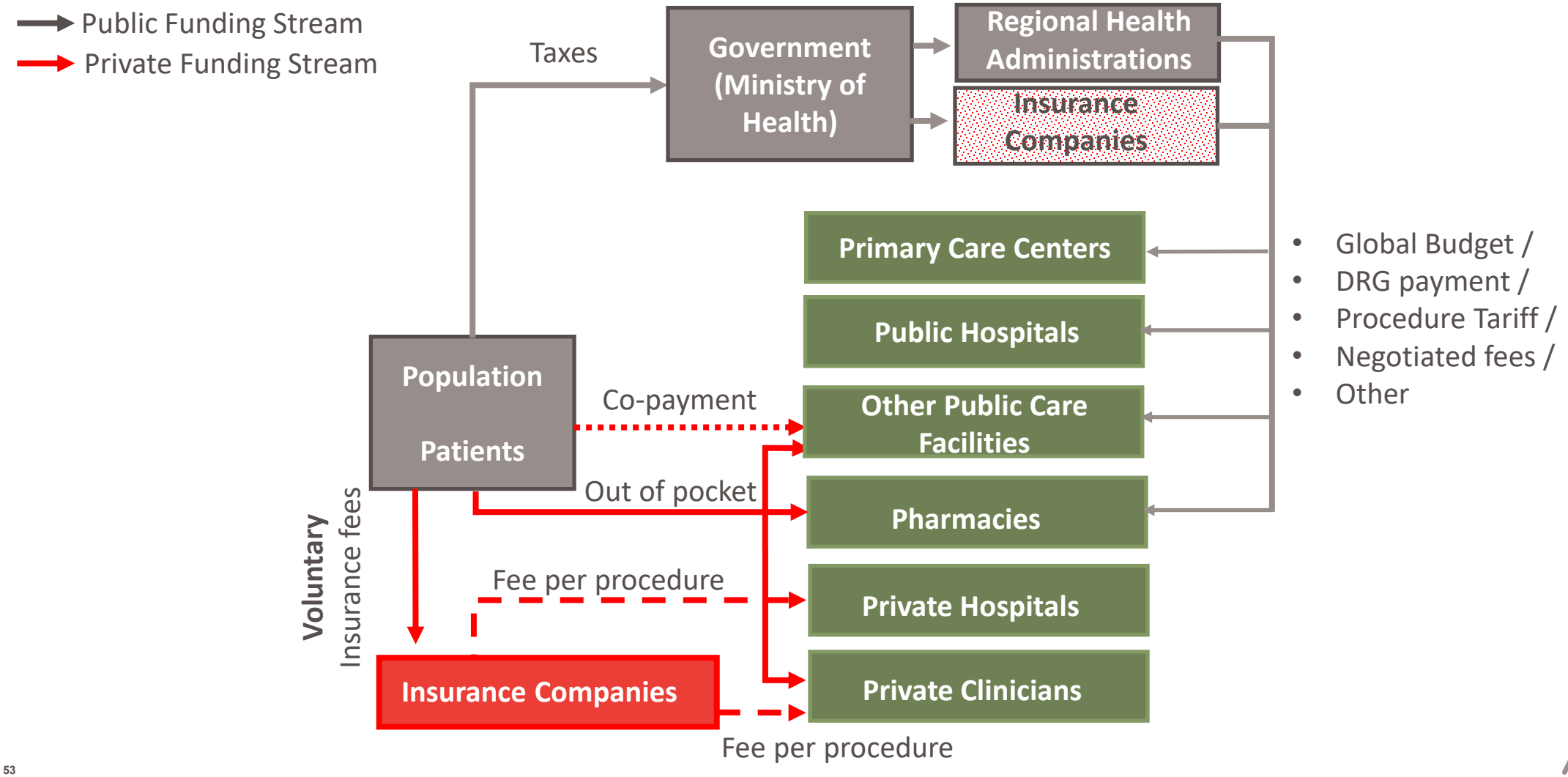
        - What DRG does this code map to?

    II. Outpatient: Does an existing ambulatory care Fee Schedule procedure code describe your technology?

Payment

Public and private payers use different mechanisms to reimburse healthcare providers for health services provided

Example of Private and Public Care Provider Funding Options



Coding for outpatient procedures
Outpatient procedures are usually coded in ambulatory care Fee Schedules

Netherlands Hospital Outpatient Fee Schedule

Passantenprijslijst 2025 - UMC Utrecht

Versie	1-jan-25
Ingangsdatum:	1 januari 2025
Einddatum:	31 december 2025

UMC Utrecht

Zorgproduct	Declaratiecode	ZorgproductOmschrijving	Tarief
OVPXXXXXX	039507	Begeleiding en interpretatie farmacologische stress-test door cardioloog bij MRI-hart inclusief voor- en nabespreking met radioloog.	691,40
OVPXXXXXX	039601	Onderzoek gevoeligheid allergenen dmv huidtest(s), met huidpriktests of intracutane injecties, per zitting.	272,66
OVPXXXXXX	039611	Extra Corporele Membraan Oxygenatie (ECMO) incl. toeslag bij behandeling op Neonatale IC of Pediatrische IC (zie 039610 voor ECMO bij behandeling van volwassenen).	4.294,74
OVPXXXXXX	039665	Standaard intra-operatieve neuromonitoring.	264,20
OVPXXXXXX	039666	Langdurige intra-operatieve neuromonitoring.	352,29
OVPXXXXXX	039667	Zeer langdurige intra-operatieve neuromonitoring.	715,22
OVPXXXXXX	039688	Uitgebreide kwantitatieve analyse electromyografisch (EMG).	164,41
OVPXXXXXX	039702	Standaard electro-encephalografie (EEG), registratie tot 1 uur.	331,34
OVPXXXXXX	039705	Langdurige electro-encephalografie (EEG), registratie vanaf 6 tot 24 uur.	1.145,66
OVPXXXXXX	039708	AMBULANTE 24-UURS ELECTRO-ENCEPHALOGRAFIE (EEG)-REGISTRATIE.	596,99
OVPXXXXXX	039709	Electro-encephalografie (EEG) bij hersendoodprocedure.	382,17
OVPXXXXXX	039712	24-UURS ELECTRO-ENCEPHALOGRAFIE (EEG)-REGISTRATIE MET DIEPTE ELEKTR.	509,08
OVPXXXXXX	039715	Aanvullende eenvoudige kwantitatieve analyse electro-encephalografie (EEG).	172,59
OVPXXXXXX	039716	Aanvullende uitgebreide kwantitatieve analyse electro-encephalografie (EEG).	170,92
OVPXXXXXX	039717	Aanvullende videoregistratie (tijdens EEG tot 1 uur).	63,42
OVPXXXXXX	039718	Aanvullende videoregistratie tijdens EEG-registratie 1-2 uur, 2-6 uur of 6-24 uur.	141,81
OVPXXXXXX	039722	ELECTRO-OCULOGRAFIE (EOG).	402,41
OVPXXXXXX	039729	Slaap-Apneu registratie (screening).	217,18

AVANIA

Coding for outpatient procedures
Outpatient procedures are usually coded in ambulatory care Fee Schedules

Coding for Outpatient Procedures - Basque Country Diagnostics Fee Schedule

A.10.I) NEUROFISIOLOGÍA

Prestación	Precio	Artículo
E.E.G. Simples	101	10001519
Electromiograma. Guía toxina botulínica.	190	10001521
Potencial Evocado (unitario). Miogénico/PEAT/PES/PEV	127	10001522
PEAT menor de 5 años	251	10018106
Multitest Potencial Evocado	378	10001523
EEG con privación de sueño	245	10003641
Blink-réflex	190	10018107
Enf. Motoneurona	378	10018108
Estimulación Repetitiva	251	10018109
Jitter	631	10018110
ERG	378	10018111
Estimulación Magnética	251	10018112

Osakidetza

ZUZENDARITZA NAGUSIA
DIRECCIÓN GENERAL

AVANIA

Outpatient Payment
Psychological tests are also subject to coverage limitations and tariffs

Reimbursement conditions
To be eligible for reimbursement under the basic package, **you must have a valid referral letter from your general practitioner** based on a suspected DSM disorder (such as depressive disorder, anxiety disorder or **cognitive disorder/dementia**). These are considered insured care. Unfortunately, **a number of DSM diagnoses are no longer reimbursed: adjustment disorders, relationship problems, phobias or work-related problems. These are considered uninsured care.**

Rates for insured care
Based on your symptoms, when a DSM diagnosis has been made and based on the care demand classification, **national maximum rates apply for reimbursement per consultation. The number of consultations you are reimbursed for depends on the care demand classification.** An average of six to eight sessions can be taken as a guideline.

Ouderenpsychologie Made

Tarieven 2025 (vastgesteld door de Nederlandse Zorgautoriteit)

Type consult	Minuten per sessie	Maximumtarief per sessie
Diagnostiek	60	€ 190,88
Behandeling	45	€ 142,29
Behandeling	60	€ 168,94

AVANIA

Inpatient Payment
Different procedures to treat the same indication may lead to different DRG's with significantly different tariffs

Procedure Coding and DRG Mapping for Ablation Treatment for Liver Cancer

ICD9 Disease Classification 155.XX "Malignant neoplasm of liver and intrahepatic bile ducts"

Procedure Type	Procedure Code and Description	DRG Code and Description	Tariff
Microwave ablation Cryotherapy	**99.85** Hyperthermia for treatment of cancer, induced by microwave, ultrasound, low energy radio frequency, probes **+ 38.19** Arterial catheterization	**203** Malignancy of hepatobiliary system or pancreas	**€3.115**
Radiofrequency ablation	**50.29** Other destruction of lesion of liver (cauterization, enucleation or evacuation of hepatic lesion) **+ 50.25** laparoscopic ablation of liver lesion or tissue	**191** Pancreas, liver and shunt procedures with complications	**€14.198**
Surgery	**50.22** Partial hepatectomy / 50.23 Open ablation of liver lesion or tissue / 50.30 Lobectomy of liver / 50.40 Total hepatectomy	**192** Pancreas, liver and shunt procedures without complications	**€8.437**
Other	50.24 Percutaneous ablation of liver lesion or tissue		

Inpatient Payment
Within a country different tariffs may apply to the same DRG code and depending on setting of care!

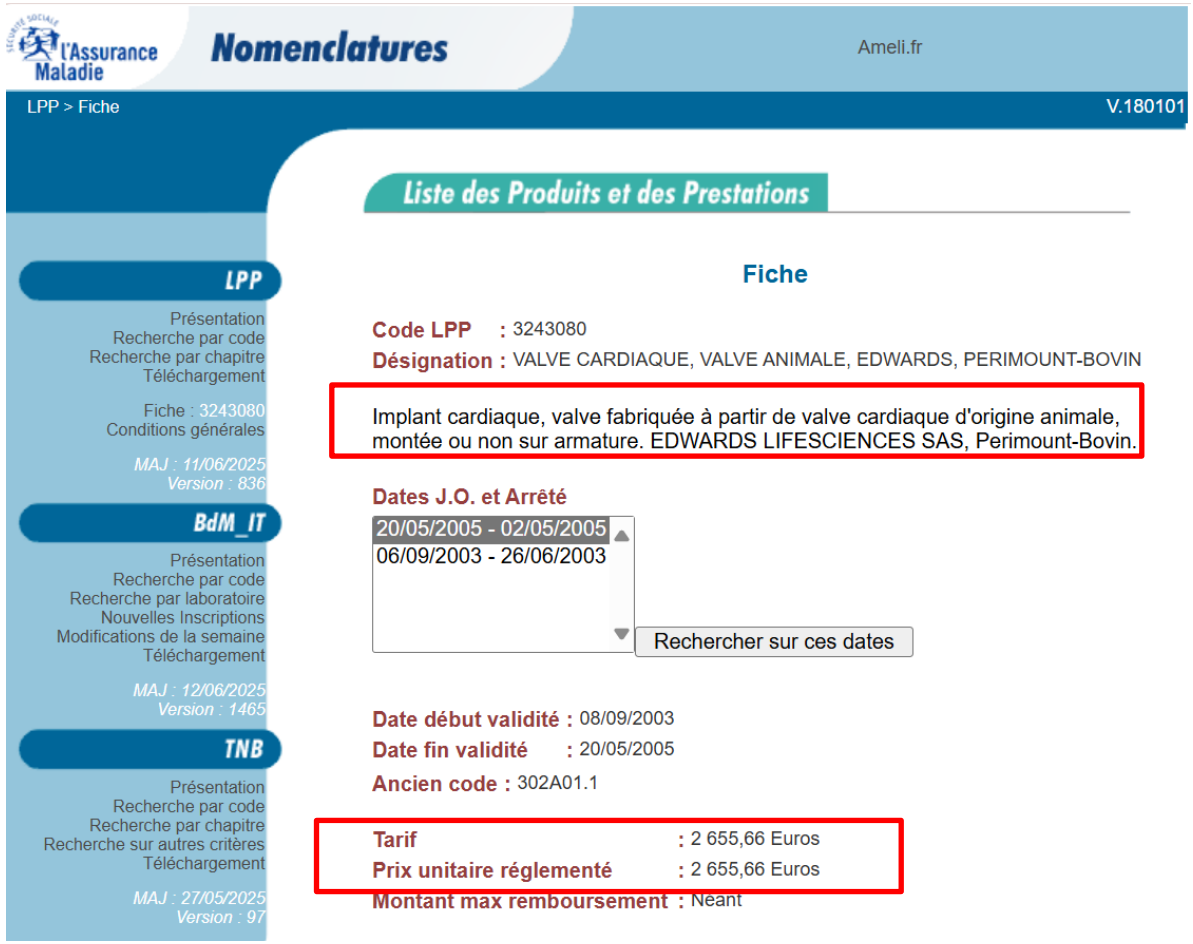
Procedure coding, DRG mapping, and Tariffs for Benchmark Bariatric Surgical Procedures

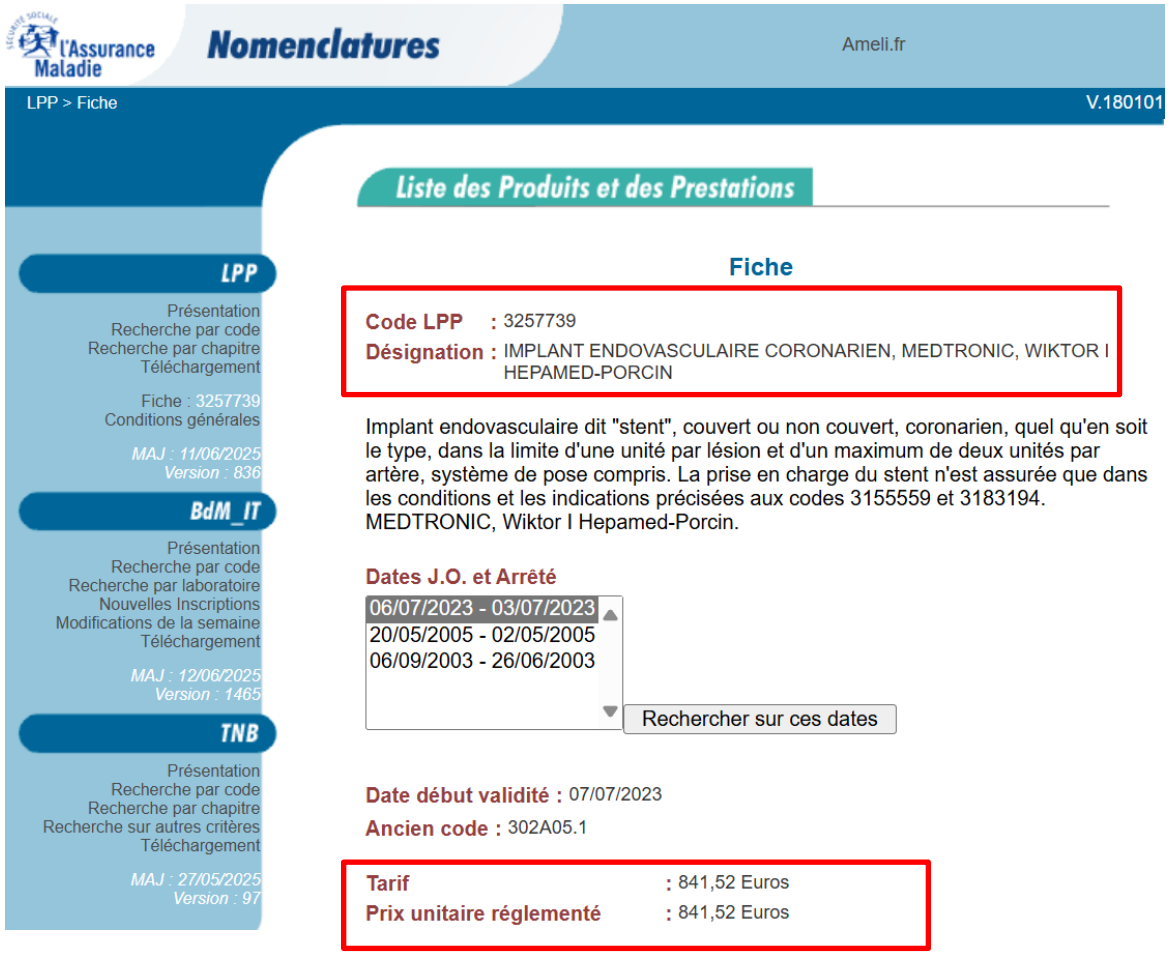
ICD9 Disease Classification 278.XX "Obesity"

Technology	Procedure Code	Tariff				
		DRG	Italy	Lombardy	Emilia Romagna	Tuscany
Gastric Balloon	44.93 Insertion of gastric balloon	**288 Procedures for obesity**				
Gastric banding	44.95 Laparoscopic gastric restrictive procedure		**Ordinary Stay:** €5.681	**Ordinary Stay:** €5.681	**Ordinary Stay:** €5.397 - €6.079	**Ordinary Stay:** €6.363
Vertical banded gastroplasty	44.68 Laparoscopic Gastroplasty		**0-1 days:** €2.518	**0-1 days:** €4.261	**0-1 days:** €2.392 - €2.694	**0-1 days:** €2.820
Gastric Bypass	44.31 High gastric bypass					
Biliopancreatic Diversion (BPD)*	43.7 Partial gastrectomy with anastomosis to jejunum 45.91 Small-to-small intestinal anastomosis					
Gastric Sleeve*	Main: 43.89 Other partial gastrectomy Other: 44.99 Other operations on the stomach					

AVANIA

Prosthesis payment
Countries may issue maximum prices for surgical implants by category or brand





Payment: Several methods to reimburse care providers for care services may co-exist within a country

Payment Methods used by a Selection of Countries

Sample Country Public Reimbursement System Analysis

Country	DRG	FFS	Global Budget
Australia (AU)	●		
Belgium (BE)		●	●
Brazil (BR)		●	●
Canada (CA)			●
China (CN)	◐	●	◐
France (FR)	●		
Germany (DE)	●	◐	
India (IN)		◐	●
Italy (IT)	●	●	●
Japan (JP)	●	●	
Mexico (MX)			●
Netherlands (NE)	●		●
Poland (PL)	●		
Russia (RU)	●	●	●
South Africa (SA)			●
South Korea (SK)	◐	●	
Spain (SP)	◐	●	●
Taiwan (TA)	◐	●	
Turkey (TK)		●	●
United Kingdom (UK)	●		

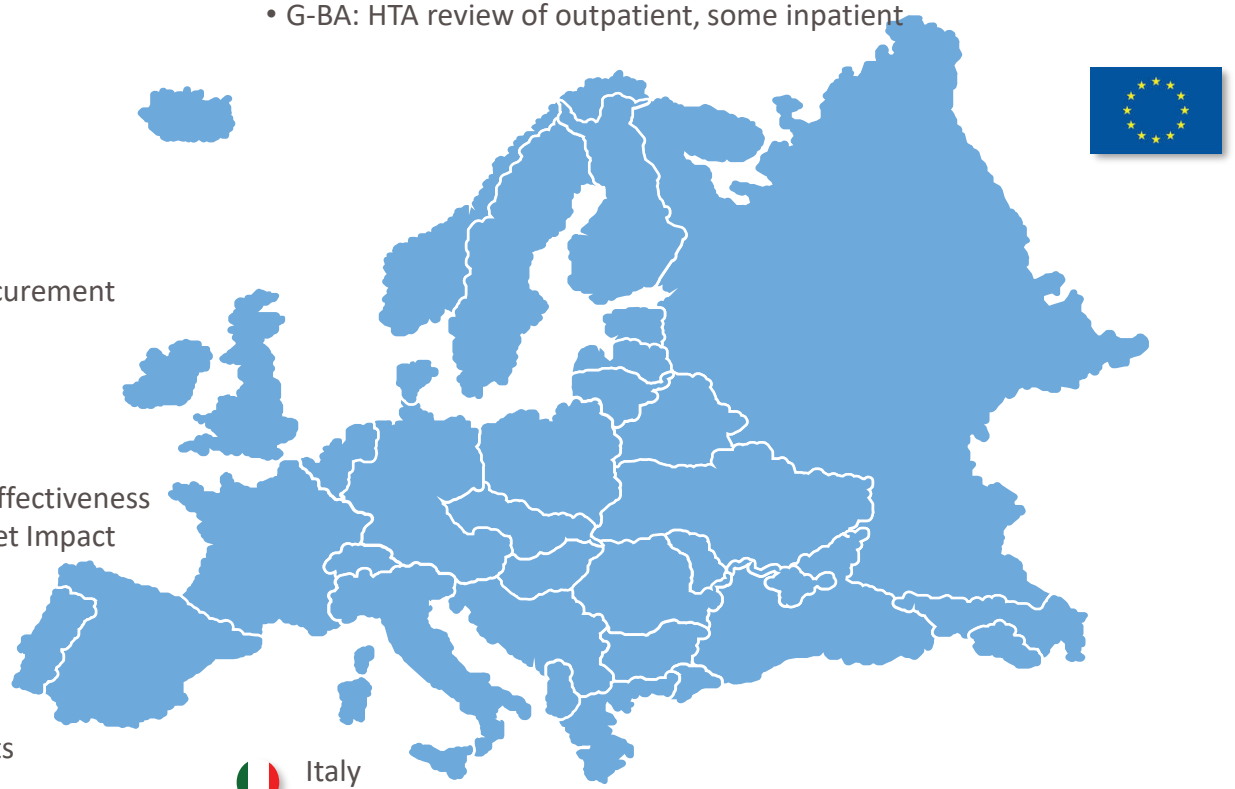
Capital equipment is treated as an investment and usually paid out of yearly healthcare provider or healthcare administrator budgets

AVANIA

The evolution of EU payment systems is shifting away from DRGs, towards more conventional budget-based funding and price volume contracts.

Germany
- Shift to outpatient: hybrid DRG's with general provision budget
- DRG-Driven
- Budget impact, cost benefit focus
- G-BA: HTA review of outpatient, some inpatient

England
- DRG-Driven
- Nationalized procurement
- NICE: Cost effectiveness
- Locally flexible payers
- Emerging Value Based Procurement



France
- DRG-Driven
- HAS: Cost effectiveness
- CEPS: Budget Impact

Spain
- Hospital annual budgets
- DRGs for tracking only
- Regional HTAs
- Emerging VBP programs

Italy
- Mix of DRG and Annual budgets
- National + Local coding
- Regional coverage and funding
- AGENAS: HTAs
- Emerging VBP programs

Payment: Questions to ask yourself for each market

The third step of a market access strategy requires defining the reimbursement system applicable to your technology in each target market

1. **How are care providers financed** for the use of your product in the aplicable setting of care?
    1. Payments related to inpatient DRG, outpatient Fee Schedule, Prosthesis coding?
    2. Annual budgets?
    3. Mix/ Other?
2. **Reimbursement:** What is the applicable reimbursement rate for your technology and will this tariff be sufficient to cover the proposed selling pice?
3. **Change process:** How transparent is the process to change the Coverage, Coding and Reimbursement system in the market of choice?
    1. Do alternative pathways exist, such as: innnovation funding, add-on payment, other?

Where coverage, coding and payment become an issue

Where coding and tariffs become an issue
A medical technology is not coded and therefore not reimbursed / the value proposition of your technology does not resonate with the reimbursment system!

Procedure coding, DRG mapping, and Tariffs for Benchmark Bariatric Surgical Procedures

Technology	Procedure Code	Tariff				
		DRG	Italy	Lombardy	Emilia Romagna	Tuscany
Gastric Balloon	44.93 Insertion of gastric balloon	**288 procedures for obesity**				
Gastric banding	44.95 Laparoscopic gastric restrictive procedure					
Vertical banded gastroplasty	44.68 Laparoscopic Gastroplasty		Ordinary Stay: €5.681	Ordinary Stay: €5.681	Ordinary Stay: €5.397 - €6.079	Ordinary Stay: €6.363
Gastric Bypass	44.31 High gastric bypass		0-1 days: €2.518	0-1 days: €4.261	0-1 days: €2.392 - €2.694	0-1 days: €2.820
Biliopancreatic Diversion (BPD)*	Main: 43.7 Partial gastrectomy with anastomosis to jejunum Other: 45.91 Small-to-small intestinal anastomosis					
Gastric Sleeve*	Main: 43.89 Other partial gastrectomy Other: 44.99 Other operations on the stomach					

- Where would the innovative “Gastric Vest” fit??
- A novel coding requirement immediately impacts the time and resource requirements – including investment in evidence - of a Market Access strategy

AVANIA

Where coding and tariffs become an issue
Example: The selling price of a medical technology exceeds the tariff

Ablation of **Neoplasm** of the Liver or Pancreas Procedure Coding and Italy Tariff

Procedure Type	Procedure Code and Description	DRG Code and Description	Tariff
Microwave ablation Cryotherapy	**99.85** Hyperthermia for treatment of cancer, induced by microwave, ultrasound, low energy radio frequency, probes **+ 38.19** Arterial catheterization	**203** Malignancy of hepatobiliary system or pancreas	**€3.115**
Radiofrequency ablation	**50.29** Other destruction of lesion of liver (cauterization, enucleation or evacuation of hepatic lesion) **+ 50.25** laparoscopic ablation of liver lesion or tissue	**191** Pancreas, liver and shunt procedures with complications	**€14.198**
Surgery	**50.22** Partial hepatectomy / 50.23 Open ablation of liver lesion or tissue / 50.30 Lobectomy of liver / 50.40 Total hepatectomy	**192** Pancreas, liver and shunt procedures without complications	**€8.437**
Other	**50.24** Percutaneous ablation of liver lesion or tissue		

- Hospitals "lose" money when the proposed selling price of a novel technology is higher than the applicable tariff. This directly affects their willingness to adopt and pay for an innovative technology.
- Requesting an Add-On tariff; Modify or Split existing DRG; apply for Innovation "pass-through" funding requires time, resources, possibly additional evidence and directly impacts the time to adoption.

Where coding and tariffs become and issue:
The selling price of your medical aid is higher than the tariff

Italy Prosthesis Nomenclator

AUSILI PER LA TERAPIA DELL'ERNIA
(AUSILI ADDOMINALI)

DESCRIZIONE	CODICE EX D.M. 28/12/92	CODICE CLASSIFICA-ZIONE ISO	EURO
L'applicazione e la fornitura di questi ausili è fatta dal tecnico ortopedico abilitato.			
VENTRIERE COSTRUITE SU MISURA			
Post - operatoria (appendicectomia, erniotomia) alta cm. 18	28.01.001	03.12.06.003	**61,46**
Per ptosi viscerale (gastrica, renale) con cuscinetto sottocoscia alta fino a cm. 30	28.01.003	03.12.06.006	**79,48**
Per sventramento semplice o per ptosi o per diastasi dei retti	28.01.005	03.12.06.009	**99,57**
Per sventramento addome pendulo, con tirante sovrapubico ed eventuali bretelle, su misura:			
- per uomo o donna fino a cm. 120	28.01.009	03.12.06.012	**139,60**
- per uomo o donna oltre cm. 120	28.01.011	03.12.06.015	**177,97**
CINTI ERNIARI SU MISURA PER ADULTI			
Possono essere forniti esclusivamente ad invalidi non operabili.			
Inguinale semplice o crurale			
- in tessuto elastico	28.05.001	03.12.06.033	**54,85**
- a molla	28.05.003	03.12.06.036	**90,79**
Inguinale doppio:			
- in tessuto elastico	28.05.005	03.12.06.039	**72,77**
- a molla	28.05.007	03.12.06.042	**101,54**
Scrotale per ernia incontenibile e sospensorio:			
- normale	28.05.013	03.12.06.045	**104,74**
- per ernia voluminosa	28.05.015	03.12.06.048	**152,82**
AGGIUNTIVI			
Foro per stomia su ventriera	---	03.12.06.103	**29,39**

AVANIA

Where coding and tariffs become an issue
An innovative technology allows a shift from inpatient to outpatient treatment which leads to a code with a significantly lower tariff!

- An important value proposition of the Greenlight or Holmium Laser Technology to treat benign prostate hyperplasia ("BPH") is that it may avoid hospitalization.
- However, the cost of the laser fibres required per procedure is > €1,250
- Existing coding and tariffs for the BPH procedure apply, with a significant difference in tariffs between the inpatient and outpatient ("day hospital") setting.
- The cost of the technology in the outpatient setting is in excess of tariffs. Therefore, the value proposition of this technology may not be applicable in certain markets.

Lazio Regional DRG Mapping and Tariffs for BPH Surgery

Code	306	307	336	337
DRG	Prostatectomy with CC	Prostatectomy w/o CC	Transurethral Prostatectomy with CC	Transurethral Prostatectomy w/o CC
Ordinary Stay	€4,953	€4,230	€3,394	€2,652
Day Hospital	€1,857	€1,121	€1,109	€1,109

Where coding and tariffs become an issue
Example: E-health application substitutes an existing – manual – procedure and the tariff is too low

- No coding available to describe automated fundus photography interpretation based on machine learning to detect diabetic retinopathy.
- Tariffs would be equal to existing, manual Fundus Photography.

Ambulatory Care Coding and Tariffs

	Code	Ambulatory Fee Schedule Description	National Tariff	Emilia Romagna	Tuscany	Lombardy
	95.03.3	Retinal Tomography (OCT)	N/A	N/A	N/A	€53.50
	95.11	**Fundus Photography**	€3,87	€4,50	€4,00	N/A
If performed by technician	**95.11.0**	**Fundus Photography (retinography) – DX Eye[1]**				€3,90
If performed by technician	**95.11.1**	**Fundus Photography (retinography) – SX Eye[1]**				€3,90
If performed by clinician	**95.09.1**	**Fundus Exam**	€7.75	€8,50	€8,00	€7.80
	95.11.1	Photography of the anterior segment	€3,87	€4,50	€4,00	€3,90
	95.12	Angiography with fluoresceine or ocular angioscopy - Retinal Tomography, IGCA[2]	€46,48	€46,50	€47,00	€46,50
	95.17	Optic Coherence Tomography, retina analysis	N/A	N/A	€90,00	N/A

1: Incl. also the method used for screening diabetic retinopathy
2: In Emilia Romagna only

Where coding and tariffs become an issue
The value proposition of your technology excedes coverage limitations!

Italy Single Use Medical Aids Nomenclator

AUSILI MONOUSO

I dispositivi medici elencati devono essere conformi al d. lgs. 24 febbraio 1997, n. 46 in attuazione della direttiva 93/42/CEE

Classe 09 "Ausili per la cura e la protezione personale"

09.18 ausili per stomia

09.18.04 sacche per stomia, a un pezzo, a fondo chiuso

dispositivi dotati di filtro antiodore, barriera protettiva autoportante in idrocolloidi o anello protettivo (in gomma naturale Karaya o diverso materiale), supporto adesivo microporoso e ipoallergenico; sul lato-corpo, rivestimento antitraspirante (in TNT o analogo materiale) e sul lato esposto, rivestimento in materiale opaco o trasparente.

		quantità erogabile
09.18.04.003	**sacca per colostomia a fondo chiuso**	60
09.18.04.006	**sacca per colostomia a fondo chiuso per stomi introflessi (stoma a filo, retratto, situato in una piega cutanea o in una cicatrice)**	60

NOTA - Le quantità massime erogabili sono da intendersi per ogni stomia e sono incrementabili, a giudizio dello specialista prescrittore, fino al 50% nel periodo iniziale di assistenza ed addestramento all'uso di durata non superiore a 6 mesi.

09.18.05 sacche per stomia, a più pezzi, a fondo chiuso

		quantità erogabile
09.18.05.003	**sistema per colostomia (placca adesiva con flangia + sacche a fondo chiuso)**	20 + 60
09.18.05.006	**sistema per colostomia (placca adesiva con flangia a convessità integrale per stomi introflessi (stoma a filo, retratto o situato in una piega cutanea e/o in una cicatrice + sacca a fondo chiuso)**	20 + 60

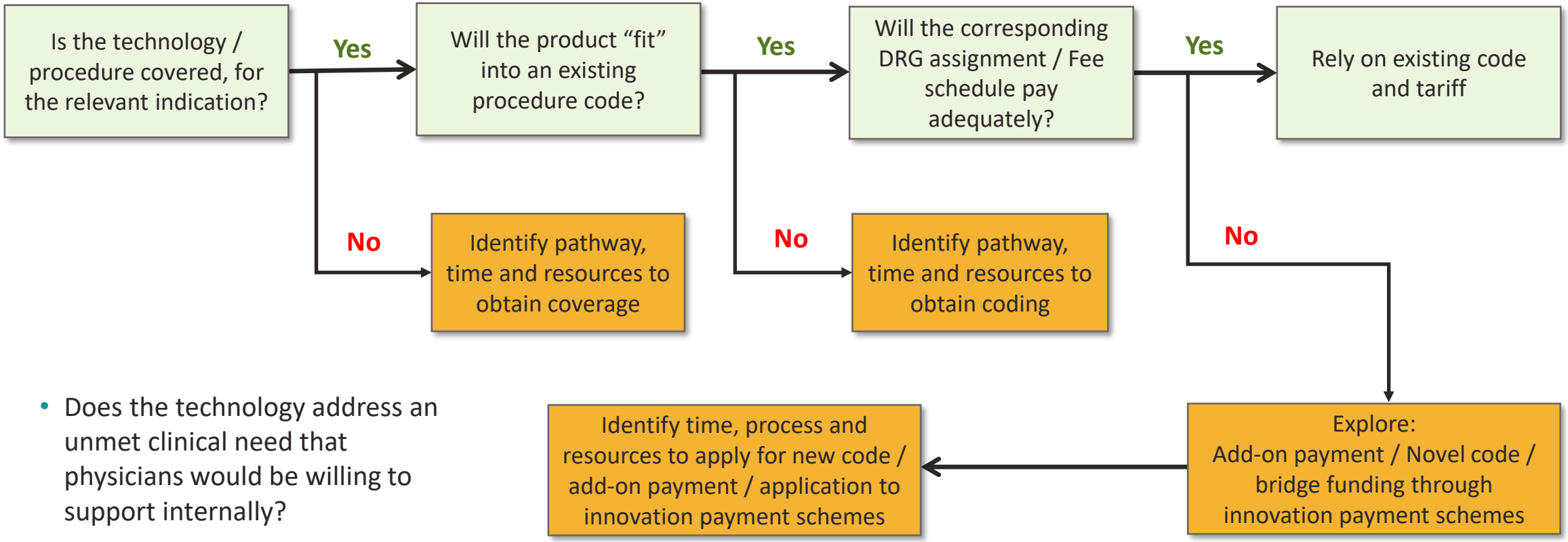
NOTA - Le quantità massime erogabili sono da intendersi per ogni stomia e sono incrementabili, a giudizio dello specialista prescrittore, fino al 50% nel periodo iniziale di assistenza ed addestramento all'uso di durata non superiore a 6 mesi.

09.18.07 sacche per stomia, a un pezzo, a fondo aperto con valvola anti-reflusso

La sacca per ileostomia deve essere dotata di filtro antiodore, barriera autoportante in idrocolloidi o anello protettivo (in gomma naturale Karaya o diverso materiale), supporto adesivo microporoso e ipoallergenico, rivestimento antitraspirante (in TNT o analogo materiale) sul lato corpo e rivestimento opaco o trasparente sul lato esposto, valvola anti-reflusso. ***La sacca per urostomia*** deve essere dotata di un sistema di scarico (preferenzialmente con rubinetto a scomparsa) raccordabile al raccoglitore da gamba o da letto, con o senza cintura di fissaggio. ***Per entrambe***, il sistema di svuotamento e di chiusura della sacca deve essere facile da usare, sicuro ed efficace nel prevenire eventuali fuoriuscite.

AVANIA

The availability of coverage and existing procedure codes as well as adequate tariffs for technology remains the key question to explore for all levels of innovation in almost every market.



- Does the technology address an unmet clinical need that physicians would be willing to support internally?
- What tools / evidence is required to support adoption and reimbursement?

Question
Are existing tariffs sufficient to cover the cost of your technology in the local market?

Funding Options in Case of Inadequate Coding or Tariffs

Characteristic	Coding	Tariff
Similar technique or procedure	Modify / Split existing DRG Code Modify Nomenclator Code	• Use existing tariff
Clearly differentiated technique	Create new DRG Outpatient Nomenclator Code	• Assist authorities define new tariff
Novel technique or procedure	Create new DRG Outpatient Nomenclator Code	• Pass through payment • Add-on tariff • Innovation Coding • Innovation funding • Special budgets

Innovation funding

Coverage Pathways for Innovations
Innovative payment schemes exist in many European countries

An innovative payment scheme is a bilateral (e.g. payer & manufacturer) or multi-lateral (e.g. payer, provider, manufacturer) agreement that provides temporary coverage and/or funding to enable patient access to medical technologies and procedures outside the general reimbursement and funding frameworks

- To date there are some 21 Innovative Payment Schemes across 8 European countries
  - 18 Coverage under Evidence development schemes +
  - 3 Unconditional innovation payment schemes
- **In over 50% of schemes a direct payment is provided to cover the cost of the technology / procedure**

Coverage Pathways for Innovations
Examples of Innovative Payment Schemes

Examples of Innovative Payment Schemes

Austria
- Provisional/analogous MEL Procedure Codes

Belgium
- Limited Clinical Application
- Validation Pyramid Level M3 Light

England
- Artificial Intelligence in Health and Care Award[2]
- MedTech Funding Mandate[2]
- NHS Innovation Accelerator[2]
- Small Business Research Initiative (SBRI)[2]
- NHS Insights Prioritization Program (NIPP)[2]
- Rapid Uptake Products (RUP)[2]

France
- Article 51 of Social Security law (2018 & 2019)
- Health Economic Research Program (PRME)
- Hospital Clinical Research Program (PHRC)
- Forfait Innovation
- Repository of Innovative Acts Outside the Nomenclature of Biology and Anatomical Pathology (RIHN)
- Remote Patient Monitoring program (ex-ETAPES)
- Transitional Coverage

Germany
- 137e - Trial Regulation
- 137h – Trial Regulation for Highly Invasive Medical Devices

... (Germany continues)
- Digital Health Applications (DiGA)
- Innovation Fund
- NUB
- Selective Contracts

Netherlands
- Innovation for Small-scale Experiments
- Promising Care
- Appropriate Care
- Efficiency Research program

Portugal
- Medical Device Reimbursement

Scotland
- IMTO Process by Health Technology Scotland
- Accelerated National Innovation Adoption (ANIA)

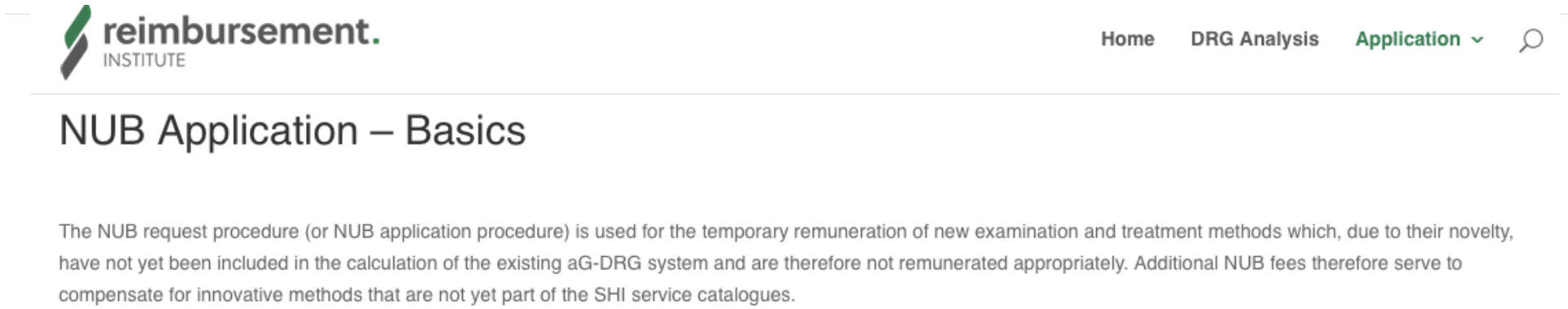
Spain
- Monitoring Studies
- Supervised Use

Switzerland
- Analogue CHOP code nomenclature
- Coverage with Evidence Development (CED)
- Individual Sickness Fund

Wales
- NHS Wales

AVANIA

Germany innovation pathway example
The German NUB provides temporary reimbursement for innovations



- Individual hospital “New examination and treatment methods” NUB applications to the InEK:
  - Before 31 October
  - hospitals submit together & **Support by a specialty society recommended.**
- If approved individual hospital negotiation of temporary supplemental fees with local SHIs.
- Technology qualification criteria:
  - **Not be properly reimbursed via existing coding and fees;**
  - **Used for less than 4 years in German hospitals; and**
  - **Cause significant additional costs for the hospital stay**.
- Some NUB items are later assigned a ZE (*Zusatzentgelt)* permanent supplemental payment if they do not otherwise “fit” into the DRG structure.

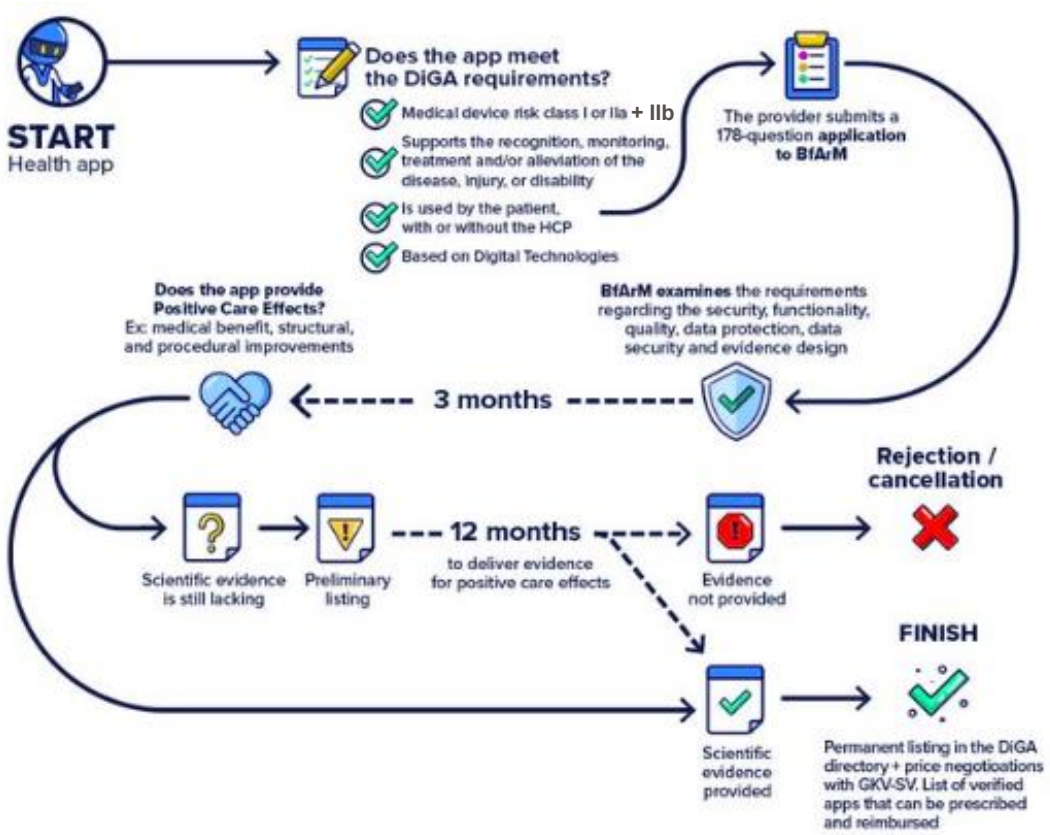
Germany Digital Health
DiGA fast track for coverage, coding and payment of Digital Health Apps

- BfArM DiGA Fast Track provides permanent or temporary **reimbursement with evidence generation.** Upon prescription
- Registration within 3 months (data protection, functionality, user-friendliness, and interoperability) with negotiated price during maximum 1 year.

DiGAs applicable for DIGA Fast Track:

- CE-marked, Risk class I or IIa **and IIb (from 2024)**
- Requires evidence of positive healthcare effects through **comparative clinical studies** .
- Main objective: digital technologies with medical purpose by way of its digital function.
- Supports the recognition, monitoring, treatment, alleviation or compensation of diseases / disabilities.

German DiGA Fast Track Process



- **Between 2019 – 2024**: **64 apps** provisional or permanent approved by BfArM: **67% of DiGA offering constitutes mobile apps**
- From 2024: **Extended to Class IIB devices. Requires submission of a prospective comparative study**. A mere improvement of a patient-relevant structure or procedure is not sufficient for the inclusion into the SHI catalogue of reimbursable products.
- On March 26, 2025, the DigiG Law came into force to accelerate the digitalization of the healthcare system. Implies increased data security requirements!

Germany Innovation Pathway example: Examples of products that have successfully made it into the DiGA directory

OVIVA

Oviva launches app on prescription for obesity across Germany

Potsdam, 18 October 2021: Oviva, the digital health scaleup which provides diet and lifestyle coaching to people who live with diet-related health challenges, is launching its first Digital Health Application (DiGA). With Oviva Direkt, the fast-growing company is focusing even more on helping people with obesity manage their weight and achieve better health through a digital solution.

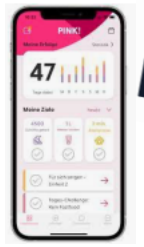
neolexon

Aphasie-App

re.flex

Rehab. At home.

re.flex is your digital therapist for knee pain. With re.flex you regain quality of life. At home, independently and wherever you want. With our patented sensor kit we help you to fight osteoarthritis-related knee pain effectively and sustainably. With measurable results in pain reduction.



PINK!, A Digital Therapeutic for Breast Cancer Patients, Is Now Reimbursed as a Prescription Digital Health Product (DiGA) in Germany

sin Cephalea

Indikationen für sinCephalea

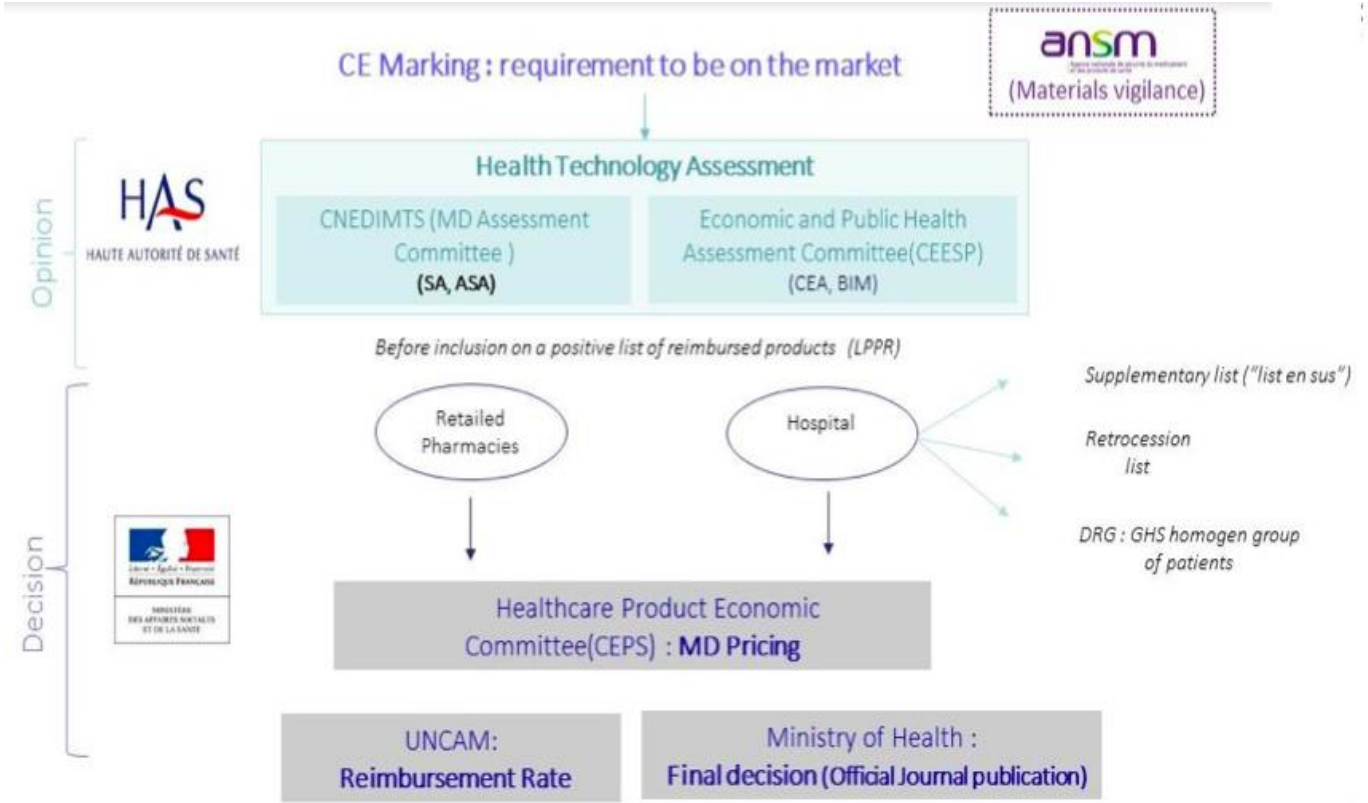
Die DiGA sinCephalea ist für Migräne zugelassen (ICD-10 G43.0 und G43.1) und kann auf Kassenrezept verschrieben werden (ref.). sinCephalea reduziert die Häufigkeit von Migräneanfällen und Belastungen im Alltag (ref.). Damit ist sinCephalea für eine prophylaktische Behandlung geeignet. Laut der aktuellen Leitlinien der Deutschen Gesellschaft für Neurologie ist eine prophylaktische Behandlung indiziert bei hohem Leidensdruck, Einschränkung der Lebensqualität oder der Gefahr, dass durch zu viele Schmerzmittel ein Kopfschmerz durch Medikamentenübergebrauch vorliegen oder entstehen könnte.

AVANIA

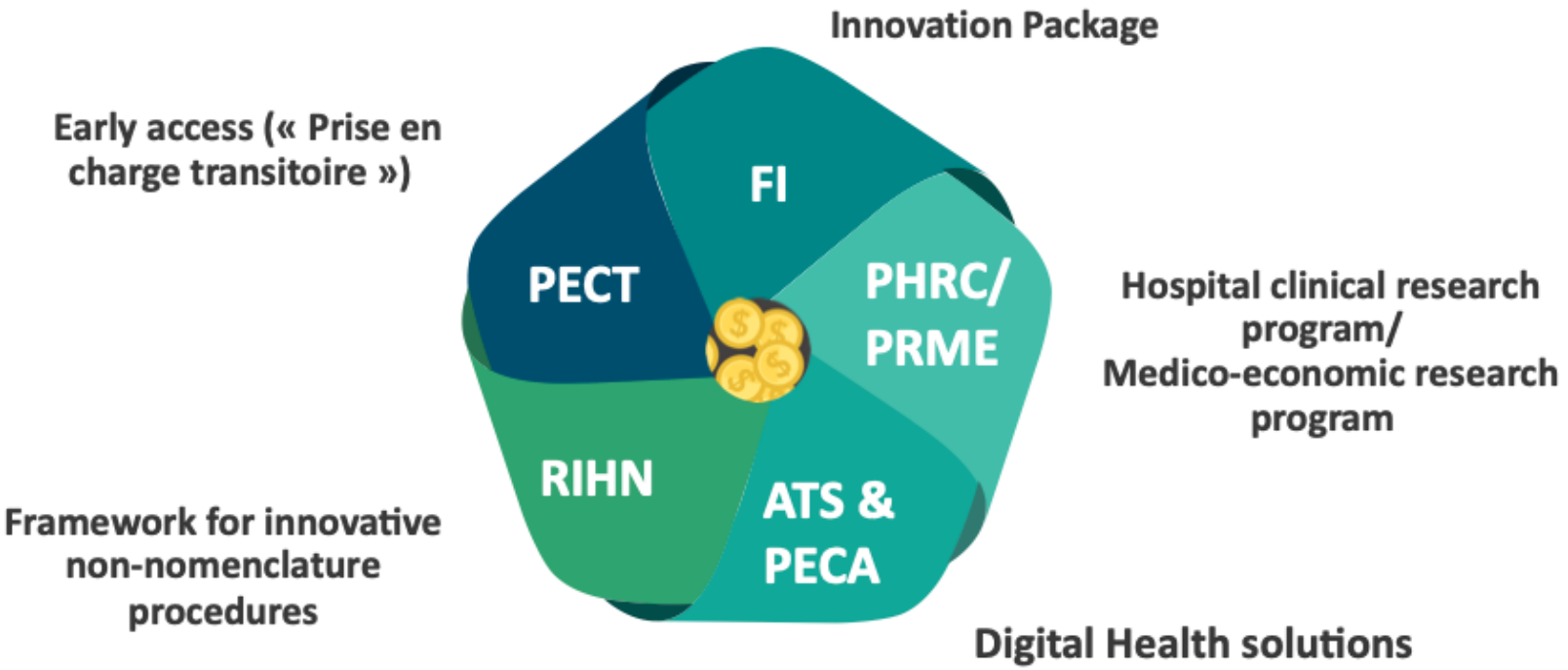
In France reimbursement of innovation pathway relies on the evaluation of comparative added clinical value

Standard P&R Process steps apply to Digital Health

1) Medico-technic assessment by the **HAS CNEDIMTs committee** provides **ASA comparative clinical added value rating, used to set reimbursement price.**
   - Digital therapeutics should demonstrate a sufficient **efficacy/safety ratio in a robust clinical study**.
2) **CEPS** committee negotiation of the digital therapeutic price.
3) **Alternative pathways** if lack of evidence: “forfait innovation”, telemonitoring experimentation (in five pathologies) or article 51.



France innovation pathway example
France has several pathways to promote innovation



France innovation pathway example
The G.NIUS PECAN program stimulates digital health innovations

PECAN is short for Prise en Charge Anticipée Numerique des Dispositifs Médicaux

(“Anticipated Reimbursement for Digital Medical Devices”)

GOUVERNEMENT
Liberté
Égalité
Fraternité

G_NIUS
Faciliter la vie des entrepreneurs en e-santé

EN | FR Accessibility

Financing eHealth regulations Ecosystems National programs What's new

Stimulating digital health innovations

- Understand the e-health ecosystem
- Identify the funding you can benefit from
- Practical content to guide you

Digital advance care (PECAN) →

Get a refund for your remote surveillance solution →

Getting reimbursed for your remote monitoring solution
6 services →

FINANCING

Early access to reimbursement for digital devices (PECAN)

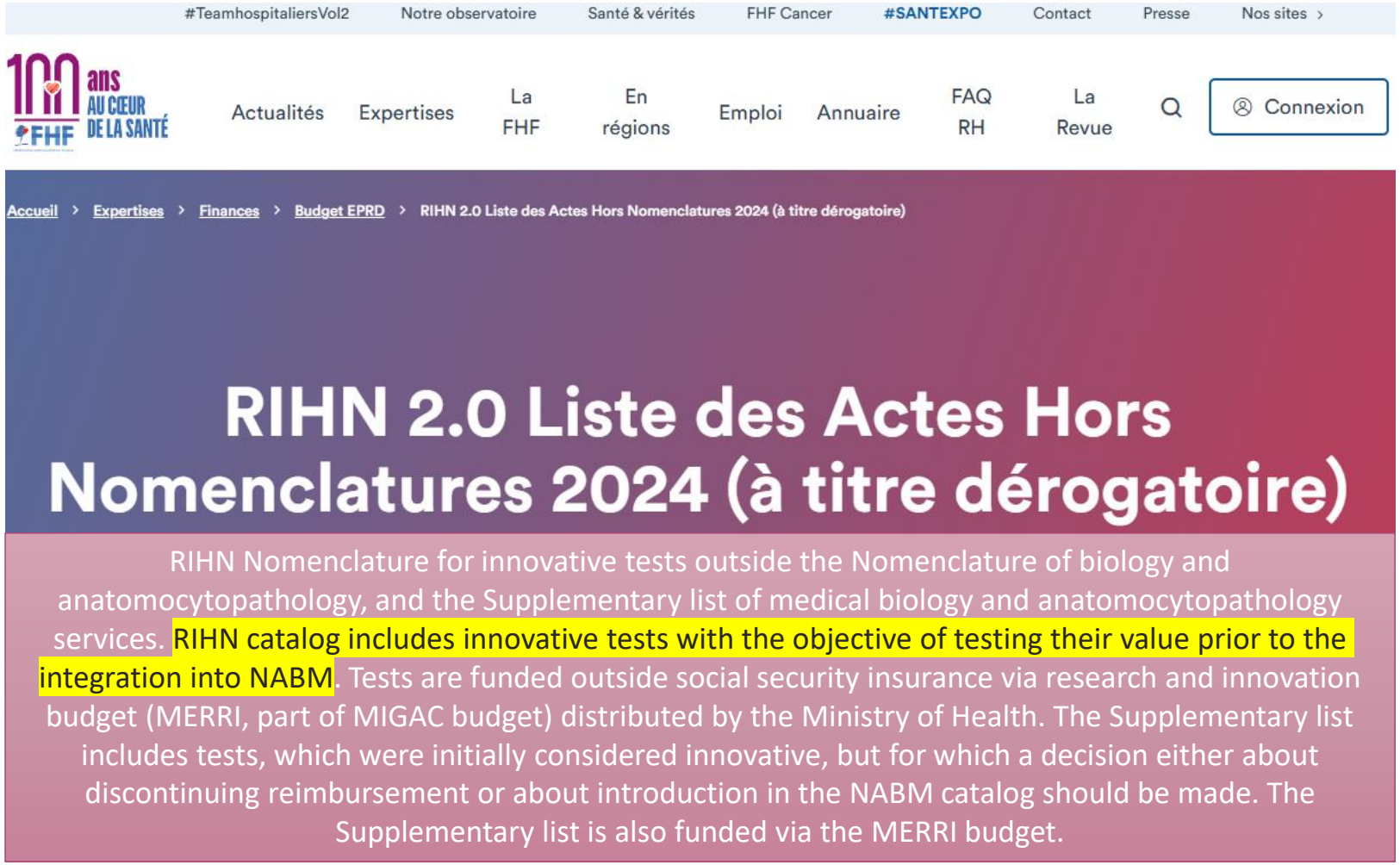
Checking to see if you're eligible for early access to reimbursement (PECAN)

DISCOVER

How to demonstrate the clinical and/or organizational benefits of your solution

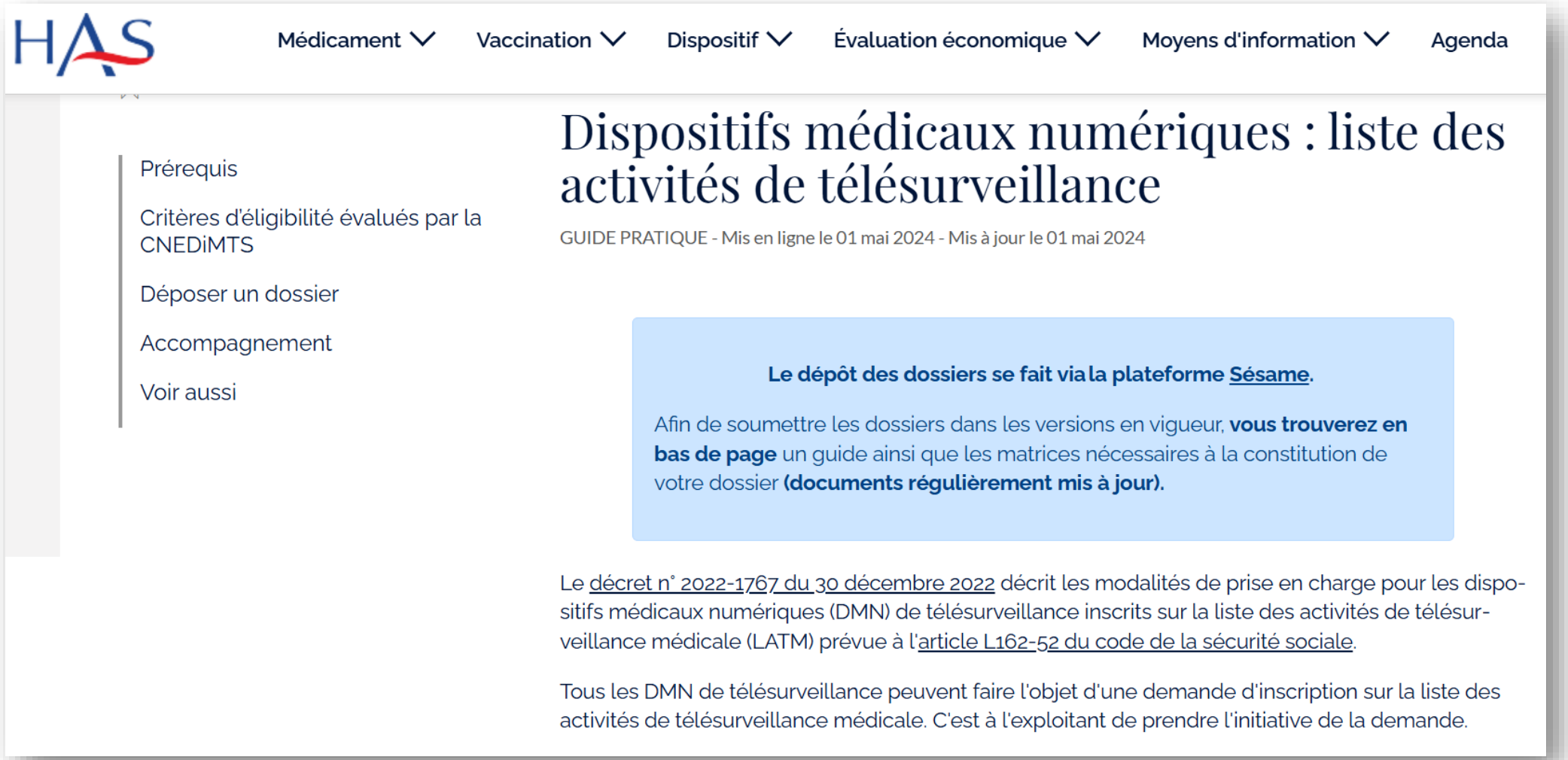
AVANIA

France innovation pathway example
RIHN Nomenclator for innovative test coverage under development scheme:



RIHN Nomenclature for innovative tests outside the Nomenclature of biology and anatomocytopathology, and the Supplementary list of medical biology and anatomocytopathology services. RIHN catalog includes innovative tests with the objective of testing their value prior to the integration into NABM. Tests are funded outside social security insurance via research and innovation budget (MERRI, part of MIGAC budget) distributed by the Ministry of Health. The Supplementary list includes tests, which were initially considered innovative, but for which a decision either about discontinuing reimbursement or about introduction in the NABM catalog should be made. The Supplementary list is also funded via the MERRI budget.

France innovation pathway example
LATM pathway examples of innovation coverage and reimbursement



HAS

Médicament | Vaccination | Dispositif | Évaluation économique | Moyens d'information | Agenda

Prérequis

Critères d'éligibilité évalués par la CNEDiMTS

Déposer un dossier

Accompagnement

Voir aussi

Dispositifs médicaux numériques : liste des activités de télésurveillance

GUIDE PRATIQUE - Mis en ligne le 01 mai 2024 - Mis à jour le 01 mai 2024

Le dépôt des dossiers se fait via la plateforme Sésame.

Afin de soumettre les dossiers dans les versions en vigueur, **vous trouverez en bas de page** un guide ainsi que les matrices nécessaires à la constitution de votre dossier **(documents régulièrement mis à jour).**

Le décret n° 2022-1767 du 30 décembre 2022 décrit les modalités de prise en charge pour les dispositifs médicaux numériques (DMN) de télésurveillance inscrits sur la liste des activités de télésurveillance médicale (LATM) prévue à l'article L162-52 du code de la sécurité sociale.

Tous les DMN de télésurveillance peuvent faire l'objet d'une demande d'inscription sur la liste des activités de télésurveillance médicale. C'est à l'exploitant de prendre l'initiative de la demande.

AVANIA

France innovation pathway example
LATM pathway examples of innovation coverage and reimbursement

deprexis®

deprexis® is a **digital psychotherapy accessible online**. Its a **software** used by patients independently, without any interface with health professionals.

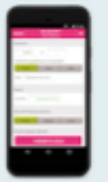
moovcare By Sivan

Moovcare® is a **web application** that detects relapse or complications during follow-up of lung cancer patients.

diabeloop

The DBLG1 System is an **external hybrid closed-loop medical device** connecting **continuous glucose monitor, patch insulin pump** and a hosting Diabeloop **algorithm**.

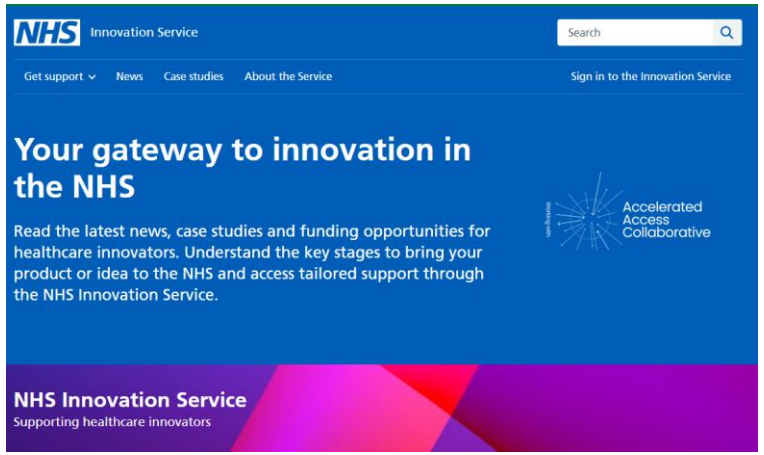
diabeo



Diabeo® is a medical device **software and associated service** to assist in processing by insulin in a basal-bolus regimen coupled with **remote medical monitoring**.

AVANIA

UK Innovation pathway examples
NHS Innovation Accelerator



Driving healthcare innovation

The NHS Innovation Accelerator (NIA) supports exceptional individuals to scale promising innovations across England's NHS for greater patient and staff benefit.

ABTRACE

Abtrace

Abtrace is a digital health software solution for GP surgeries that sits on top of existing electronic healthcare record systems extracting data, processing against guidelines, delivering an intuitive output to clinicians and managers.

Early diagnosis and prevention

pinpoint

Pinpoint Test

The PinPoint Test is an Artificial Intelligence (AI)-driven, affordable blood test for cancer, designed to optimise NHS urgent cancer referral pathways. It has the potential to transform the patient experience, reduce systemic overloading and allow clinicians to focus their time on the patients that need them most.

OpenMedical

Pathpoint eDerma

Pathpoint eDerma is a cloud-based teledermatology system that streamlines both acute ward referrals and GP 2ww (2 week-wait) cancer pathways. The platform supports the entire patient pathway from initial referral in primary and secondary care to management and discharge.

CARDMEDIC
FLUENT IN HEALTHCARE

CardMedic

CardMedic is an inclusive communication app that enables clinicians and patients to overcome communication barriers at any time. The app provides a rich, growing library of pre-scripted, pre-interpreted conversations that are commonly had between patients and clinicians, which can be converted into 44 languages and formats, including sign language.

braininhand
personal technology for independent living

Brain in Hand

Brain in Hand uniquely combines user-led self-management, human support and digital tools to empower people with autism and neurological difference to live more independently.

Mental health

itecho health

Ascelus

Ascelus is an AI (Artificial Intelligence) powered digital platform that integrates with hospital IT systems to improve the management of long-term conditions (LTCs). Patients are able to record their own insights and receive clinical advice/test results via their smartphone/device.

AVANIA

UK Innovation pathway examples
NHS Insights Prioritisation programme (NIPP)

NHS Insights Prioritisation Programme (NIPP)

Supporting post-pandemic priorities

The NHS Insights Prioritisation Programme (NIPP) was set up to accelerate the evaluation and implementation of promising innovations – selected for their potential to support the evolution of post-pandemic ways of working, build service resilience and deliver ongoing benefits to patients.

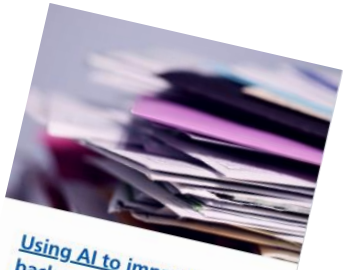
Working together to generate insights for ICSs

Launched in 2021 by NHS England and the NHS Accelerated Access Collaborative (AAC), the programme invited AHSNs and Applied Research Collaborations (ARCs) to bid for a share of £4.2m investment to test and evaluate promising innovation within their Integrated Care Systems (ICSs).

Each of the AHSN and ARC projects is now gathering momentum and will demonstrate impact on health inequalities, focusing on one of four priority areas:

- Remote consultation
- Remote monitoring
- New approaches to service delivery
- Health and social care workforce innovation

UK Innovation pathway
Artificial Intelligence in health and Care Award

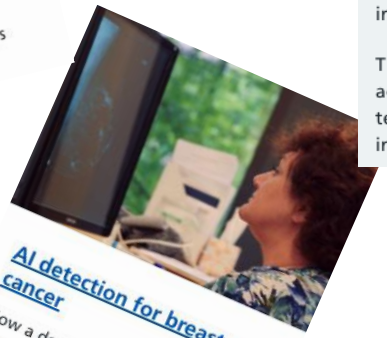


Using AI to improve back office efficiency

Read about the role of AI in helping the NHS to maximise resources and reduce patient waiting times.

Smartphone self-testing

Find out how patients are benefitting from AI that helps detect early kidney disease.



AI detection for breast cancer

How a deep learning tool analyses mammograms to support breast screening.

NHS England - Transformation Directorate

The Artificial Intelligence in Health and Care Award

The AI Award is funding and supporting promising AI technologies for health and social care.

The Artificial Intelligence (AI) in Health and Care Award aims to benefit patients by combining the power of artificial intelligence with the expertise of the NHS to improve health and care outcomes.

The Award has committed £123 million to accelerate the testing and evaluation of technologies most likely to meet the aims set out in the NHS Long Term Plan.

The AI in Health and Care Award is increasing the impact of AI systems in helping to solve both clinical and operational challenges across the NHS, including reducing waiting times, improving early diagnosis and saving staff time. It will speed up the most promising technologies through the regulatory process by building an evidence base to demonstrate the effectiveness and safety of artificial intelligence in health and care.

AVANIA

Netherlands Innovation Pathway: The Dutch government strongly supports innovation in healthcare

Health Deals

Rijksoverheid

Effectieve en breed toepasbare vernieuwing in de zorg voltrekt zich nooit vanzelf. Een Health Deal brengt daar verandering in. Health Dealskunnen zorginnovaties helpen meer te bereiken. Met een duidelijk doel en heldere afspraken bevorderen (private) partijen en de overheid vernieuwing in de zorg. Ook zetten zij zo de nodige stappen om de (patiënten)zorg beter en betaalbaar te maken.

Health Deal 'Beslisondersteuning in de oncologie'

De Health Deal 'Beslisondersteuning in de oncologie' helpt artsen en patiënten in de toekomst bij het maken van de beste keuze voor een behandeling. In de Health Deal werken verschillende partijen samen om de relevante kennis op het juiste moment op een handige manier ter beschikking te hebben.

Health Deal 'Langdurige zorg

De Health Deal 'Langdurige zorg' gaat over de ontwikkeling en de inzet van nieuwe technologie voor mensen met een beperking. Publieke en private partijen slaan de handen ineen. Hierdoor komen vernieuwende én kostenbesparende zorginnovaties tot stand. Dat doen de partijen samen met Academy Het Dorp, opgericht door Siza.

Health Deal 'Chronische Pijn'

Het doel van de Health Deal 'Chronische pijn' is toepassing van een nieuwe zorgstandaard chronische pijn. Deze standaard moet leiden tot hogere gezondheidswinst voor de chronische pijnpatiënten. En 20% lagere zorgkosten, schadelast en maatschappelijke kosten.

Health Deal 'Persoonlijke preventie'

In 2020 gebruikt 10% van Nederland e-health voor persoonlijke preventie. Dat is 1 van de concrete doelen van de '↗Health DealStimulering gezondheid door persoonlijke preventie via e-health.'

Netherlands Innovation Pathway: Many innovations can be covered, coded and reimbursed through the standard DBC coding system

Since January 2023: Add-on coding for Telemonitoring
Overig Zorgproduct: 039133 “Telemonitoring”

CROHN & COLITIS NL
Met elkaar sterker

mijnIBDcoach

‘Financiering is doorbraak voor e-healthproject voor IBD-patiënten’

Samen met de patiëntenvereniging Crohn-colitis.nl en collega’s uit zowel academische als niet academische ziekenhuizen zette maag-darm-leverarts Marieke Pierik in het MUMC+ een e-healthproject op voor patiënten met chronische darmontstekingen (IBD). Financiering was er aanvankelijk niet voor. Sinds 1 januari wordt het nu toch vergoed. 'Een doorbraak.'

AVANIA

Netherlands Innovation Pathway
Several websites offer client friendly assistance for developers of health innovations

Zorg van Nu

Guide to Care Technology, e-health and digital care

Physiotherapy
Examples care providers

- ActiFytaal ↗
- SocialFysio ↗
- Fit Thuis ↗
- Join2Move ↗
- AudioFysio ↗
- FysioSupplies ↗

For physiotherapists

- MijnZorgApp ↗
- Physitrack ↗

AVANIA

Netherlands Innovation Pathway example: Innovations for Small-Scale Experiments

Innovations for small-scale experiments facilitate the collaboration between providers and insurers in small-scale experiments

The program applies to innovative procedures/programs that improve the quality of care or the efficiency (price/quality).

Innovatie

De beleidsregel 'Innovatie ten behoeve van nieuwe zorgprestaties' heeft als doel zorgaanbieders de ruimte te geven om kortdurend en kleinschalig te experimenteren met innovatieve zorgprestaties. Een innovatieve zorgprestatie is een prestatie die nog niet eerder door de NZa is vastgesteld als reguliere zorgprestatie.

Netherlands Innovation Pathway
Insurance companies evaluate and support coverage of health innovations

Netherlands Innovation Pathway example
Insurers can cover care services beyond those covered at national level through pilot programs

Evaluation period ends

Together with VGZ, we are offering the possibility in a pilot to have Qups reimbursed from the basic insurance. This applies to all insurers affiliated with Coöperatie VGZ. This scheme will run until 31 December 2022. After that, the option expires because we choose it ourselves.

Qups no longer reimbursed

Spain Innovation Pathway example
Monitoring Studies to evaluate coverage of innovations through the Common Service Portfolio

Jornadas científico-técnicas abiertas de la RedETS

COOPERACIÓN PARA AFRONTAR LOS NUEVOS RETOS EN EVALUACIÓN DE TECNOLOGÍAS SANITARIAS EN ESPAÑA Y EN EUROPA

16-17 de Noviembre 2017 (Tenerife)

Red Española de Agencias de Evaluación de Tecnologías y Prestaciones del Sistema Nacional de Salud

Osteba

Estudio de Monitorización: "Sistema de reparación percutáneo de la válvula mitral mediante clip" Resultados de los primeros 6 meses de seguimiento

José Asua, Anai Moreno, Eva Reviriego.

Introducción

Desde la obtención del certificado de Conformidad Europea en 2008, se han implantado más de 20.000 dispositivos de cierre mitral percutáneo mediante Clip en Europa. De ellos, aproximadamente 750 han sido en España. Desde entonces se han publicado varios informes de seguridad, eficacia y coste-efectividad del dispositivo por diferentes organismos independientes, en su mayoría de ámbito internacional.

Sin embargo, no existía hasta la actualidad en España un Estudio de Monitorización (EM) que permitiese conocer el perfil del paciente al que se le implanta un dispositivo de este tipo, cuáles son los resultados del mismo en la salud de los pacientes y cuál es el impacto que supone para el Sistema Nacional de Salud (SNS).

Objetivos

- ✓ **Describir el perfil de paciente al que se le implanta Clip Mitral.**
- ✓ **Valorar la seguridad.**
- ✓ **Valorar la efectividad a medio y largo.**
- ✓ **Valorar el coste-efectividad.**

En el marco de la cartera común de servicios del SNS.

Spain Innovation Pathway example: Regional Innovative Public Procurement funding exists to incorporate healthcare innovations in clinical practice

Spain Innovation Pathway example:
Market access and reimbursement for innovations is based overall on local initiatives

‘MHEART’, UNA ‘APP’ PARA MEJORAR LA ADHERENCIA POSTRANSPLANTE

HOSPITAL DE LA SANTA CREU I SANT PAU

El Servicio de Farmacia y la Unidad de Transplante Cardiaco del Hospital de la Santa Creu i Sant Pau han desarrollado, con el apoyo tecnológico de Nabelia y el patrocinio de Astellas, una app que ayuda a mejorar la adherencia de estos pacientes.

‘FARMAVENTURA’, UN PROYECTO LÚDICO CON IMPLICACIONES PARA LA ADHERENCIA

HOSPITAL MATERNO INFANTIL GREGORIO MARAÑÓN, EN MADRID

El Servicio de Farmacia del Hospital Materno Infantil Gregorio Marañón ha impulsado un proyecto para mejorar la adherencia en menores a través de cuentos, juegos y ejercicios didácticos.

‘ADHAN’: EL USO DE INTELIGENCIA ARTIFICIAL PARA PREVENIR FALTAS DE ADHERENCIA

HOSPITAL UNIVERSITARIO RAMÓN Y CAJAL

Teresa Gramage, farmacéutica especialista del Hospital Ramón y Cajal, explica a Diariofarma el proyecto Adhan, basado en la aplicación de la inteligencia artificial para prevenir la falta de adherencia a antineoplásicos orales.

Private Sector
Private health insurers across Europe provide funding and support for health innovations

Innovation Pathways Take Away's

1. Most countries count with specific pathways to support the adoption of medical device innovations that:
   - **Lack sufficient evidence** to determine positive coverage decisions
   - **Do not "fit" in the current healthcare coding and reimbursement system**

2. Almost all of these pathways rely on the **evaluation, or prospective collection of clinical and health economic evidence**

3. For companies wishing to apply it is important to **understand the evidence requirements of these processes and to invest in collecting the "right" type of evidence required.**

Market Access Strategy Development

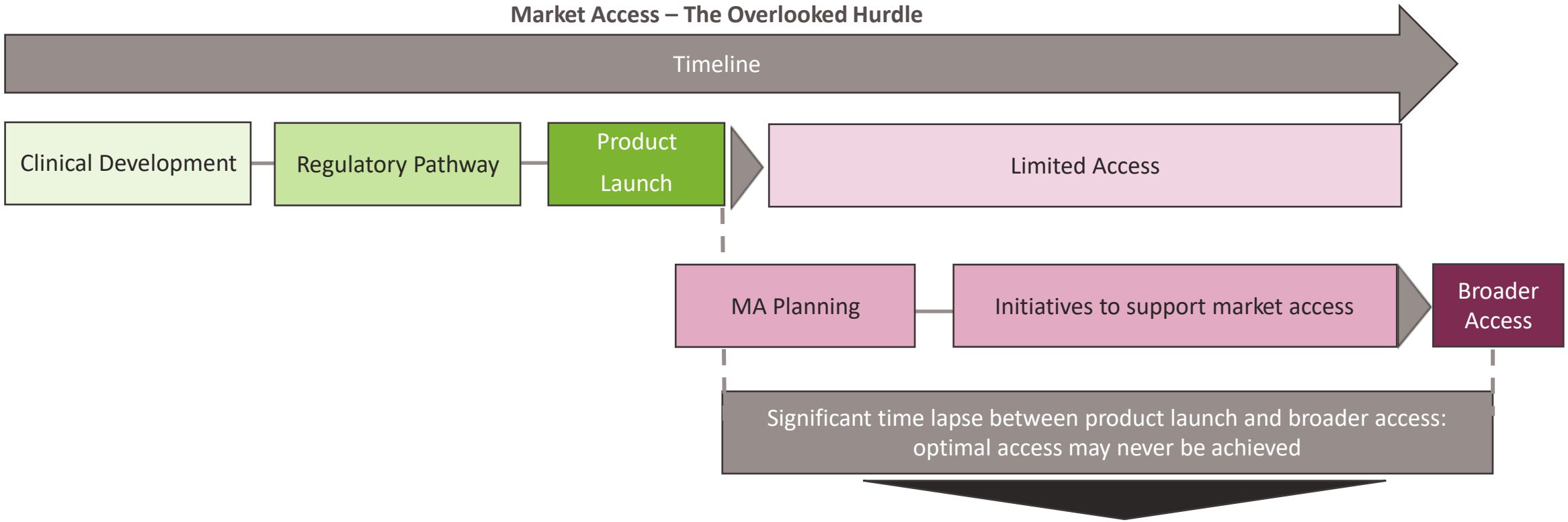
- Timeline
- Stakeholder Value Proposition Criteria
- Steps and strategic assessment stages

Market Access Strategy Development

- Timeline

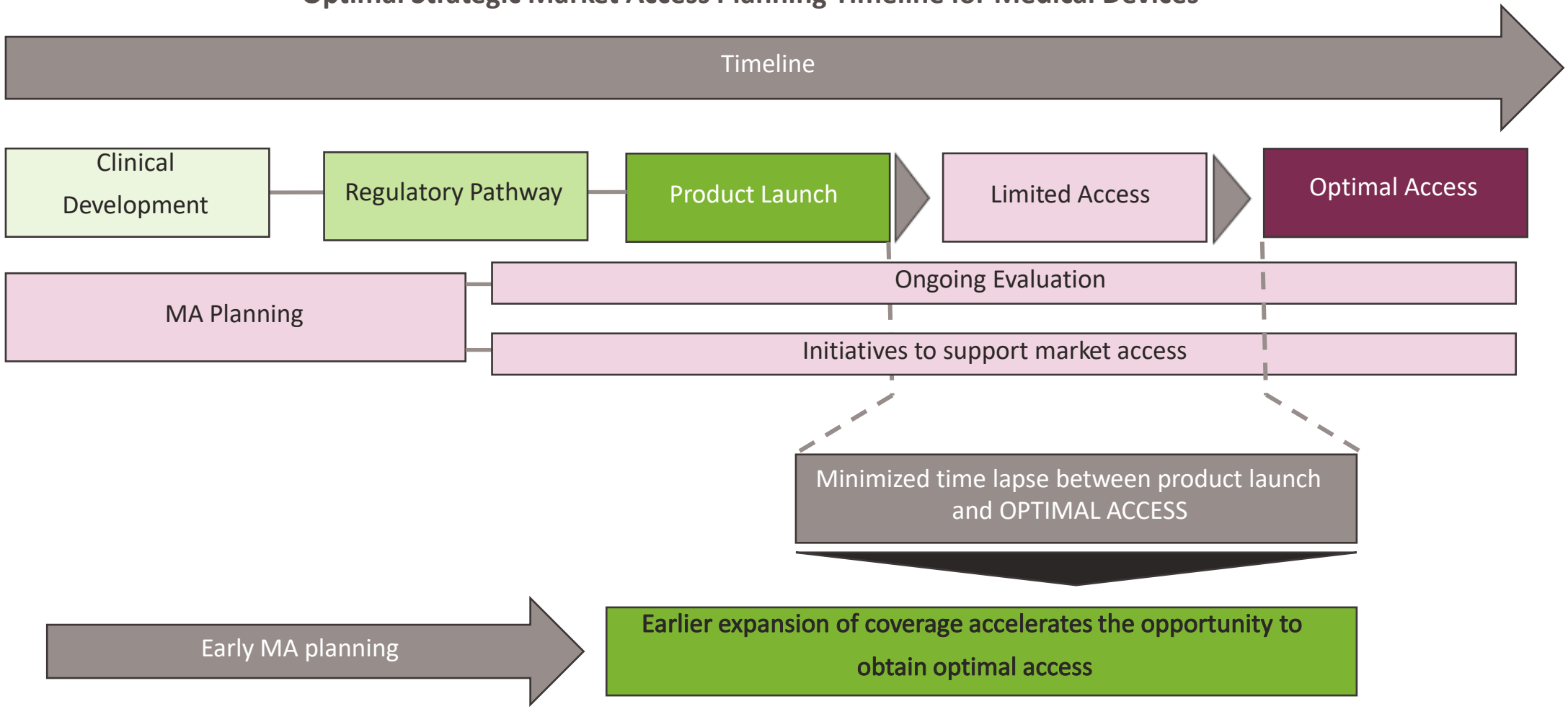
Lack of timely Market Access planning leads to uncertainty as to market size and time to market from an investor due diligence perspective

- Often market access planning is initiated late in the product life cycle: At that point it largely consists of reactive efforts after launch to rectify existing limitations



Investors will want to understand which strategic market access planning activities and resources are required to ensure **optimal** market access and reimbursement

Optimal Strategic Market Access Planning Timeline for Medical Devices



Companies need to think about Market Access and Reimbursement throughout the product lifecycle

Strategic Market Access and Reimbursement analysis is required throughout the Product Lifecycle Stages

It informs of expected time and resource requirements to obtain market access, including in terms of evidence collection

Product Lifecycle Stages

Market Access and Reimbursement Analysis Scope by Product Stage

✓	x	✓	✓	x	✓	✓
• Early Market Access and Reimbursement pathway analysis • Initial evidence plan		• Integrated clinical and resource utilization evidence design • Confirm critical path requirements	• Health economic evidence design and generation.		• Coordinate stakeholder support • Support RWE collection	• Apply for novel codes / coverage under evidence development • Design and support reimbursement • Dossiers for coverage / HTA reviews • Lifecycle MA&R support

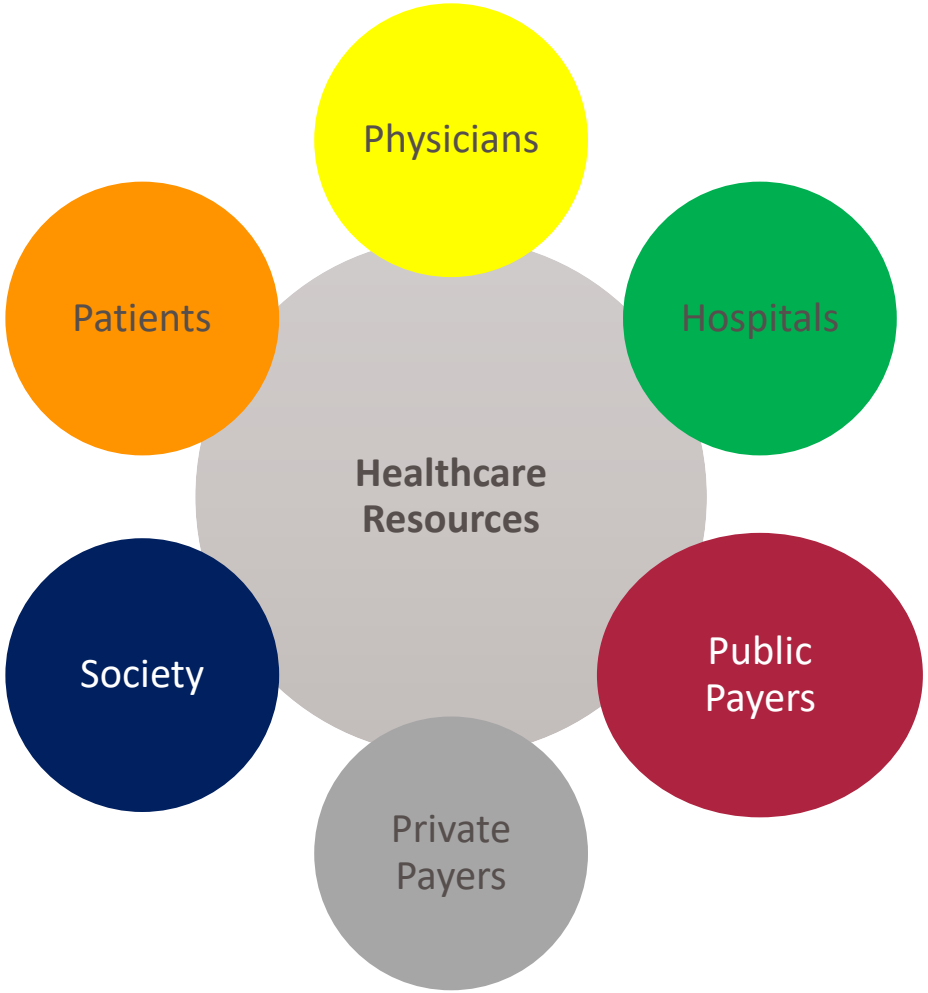
AVANIA

Market Access Strategy Development

- Stakeholder Value Proposition Criteria

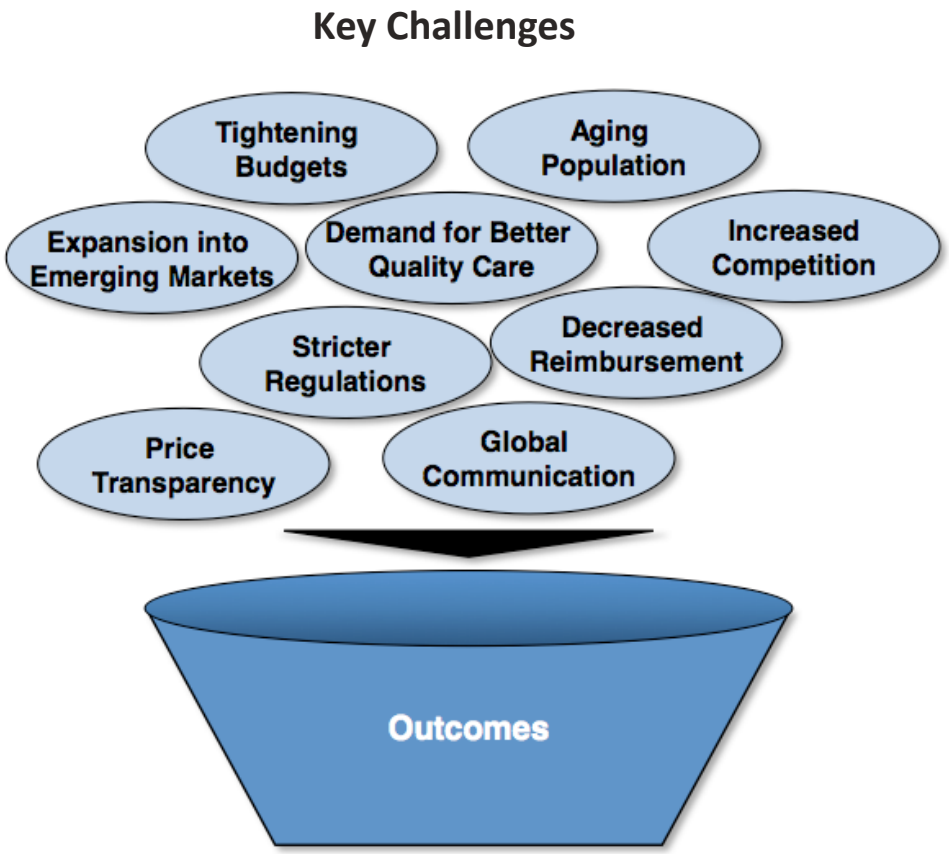
Question: MedTech market access is affected by a variety of stakeholders; Can you identify the relevant key stakeholders for your technology in the target market?

- Priorities, and approach to allocation of healthcare resources and coverage of healthcare services depends on individual stakeholder needs and perspectives.



The – comparative - value proposition of a technology will need to be demonstrated to the relevant stakeholders

- Within the context of providing more care with equal or less resources it is of paramount importance to demonstrate the value of innovative medical devices to relevant stakeholders
- Strong value demonstration needs to address payers' concerns in each market to achieve the critical clinical and economic benchmarks necessary to gain optimal market access



Market access stakeholders:
Examples of value criteria from a hospital administrator perspective

"Value" from a Health Administrator Perspective	
Patient Health Benefits & Legal Compliance	↑ Quality of care & QALY ↓ Mortality ↓ Morbidity
Productivity & Efficiency	↑ Workflow ↑ Patient throughput • "Doing more / same, cheaper"
Reputation	• Attract patients / clinicians • Hospital / clinician reputation
Profitability	↑ Workflow ↑ Return on Investment

AVANIA

Market access stakeholders:
Examples of value criteria from a payer perspective

"Value" from a Payer Perspective	
Health Benefits for Patients	↑ Quality of care & QALY ↓ Mortality ↓ Morbidity
Benefits for Health Care Systems	↑ Efficiency, quality and organisation of care • Cost effectiveness, budget impact • Opportunity cost • Net gain on public health and wellbeing
Benefits for Society	↑ Productivity ↑ Population health • Support for disadvantaged population groups (rare diseases,…) • Benefits for innovative technology sector
Non health benefits for Patient and Caregiver	↓ Costs to return to work ↓ Burden of Care

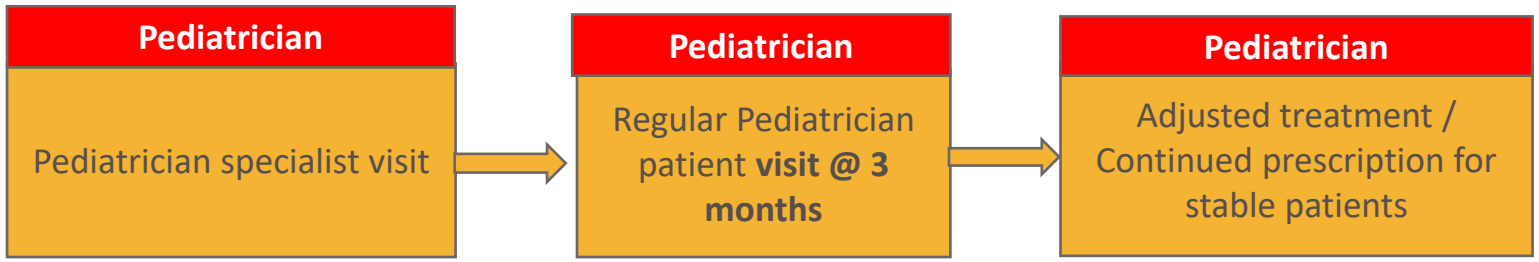
AVANIA

Question: Resource allocation is evaluated by each stakeholder with their own perspective of "Value": How do stakeholders in your target market perceive the – comparative - value of your device?

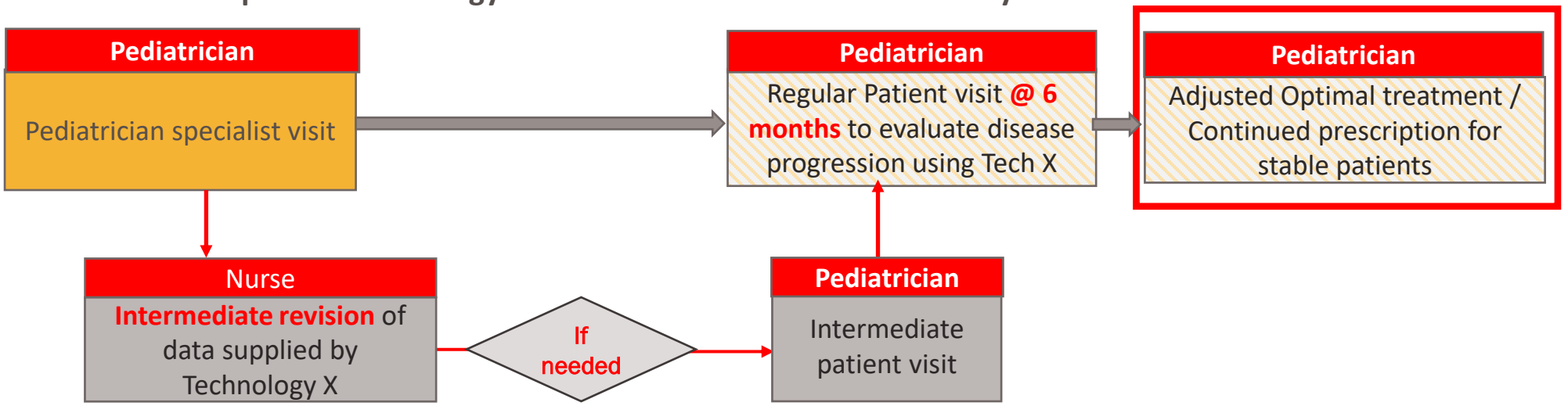
"Value" from a Clinician Perspective	
Health Benefits for Patients	↑ Safety & Efficacy ↑ Patient outcomes ↑ Quality of care & QALY ↓ Mortality ↓ Morbidity
Benefits for Physician	↑ Physician payment ↑ Reputation ↑ Attract patients ↑ Ease of use
Benefits for organization	↑ Efficiency, quality and organisation of care ↑ Reputation
Benefits for Society	↑ Population health

Ultimately, the value of your technology will be compared by stakeholders to standard of care in terms of changes in effectiveness and cost

SoC Patient Treatment Pathway & Clinical Stakeholders



Impact of Technology X on SoC Patient Treatment Pathway & Clinical Stakeholders



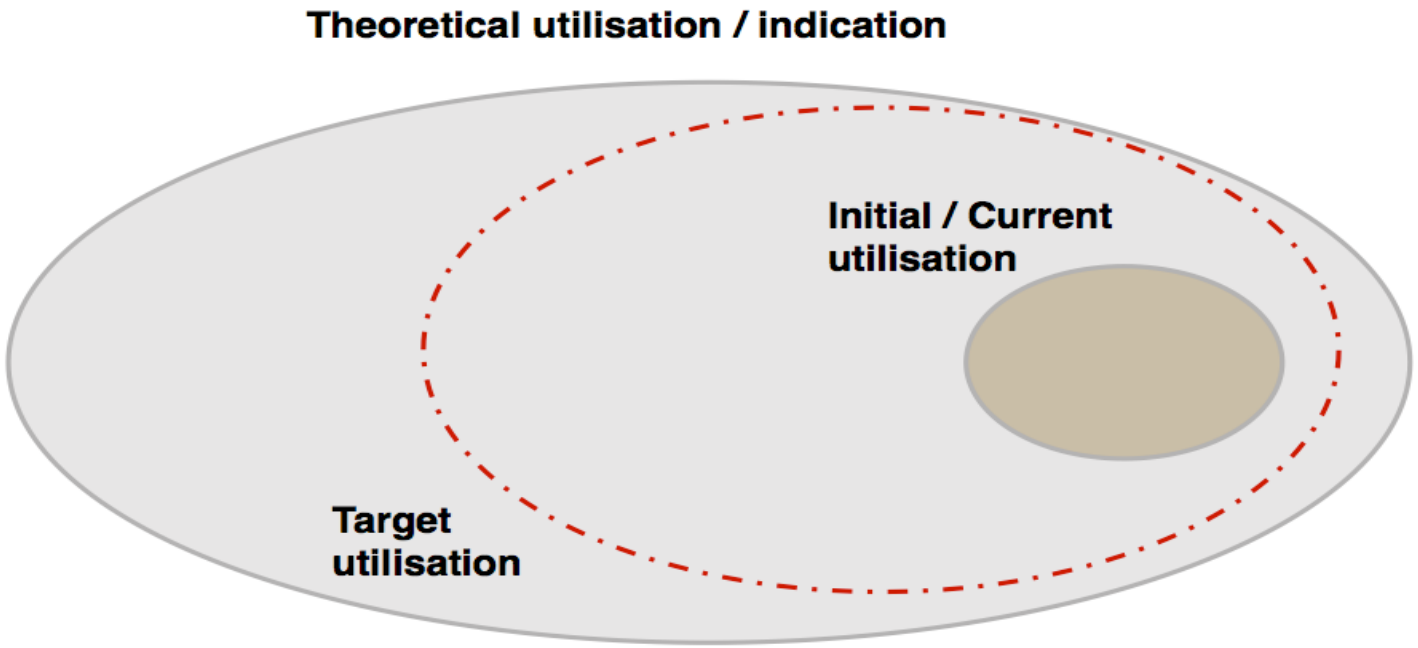
Market Access Strategy Development

- Steps and strategic assessment stages: Target Indication

Market Access Steps
Question: Based on the value proposition of your technology, what is the target indication and the initial utilisation?

Think about:

- Subset of patients with specific characteristics,
- A specific stage of a pathology
- Type of treatment center
- Particular Key Opinion Leaders
- Other?

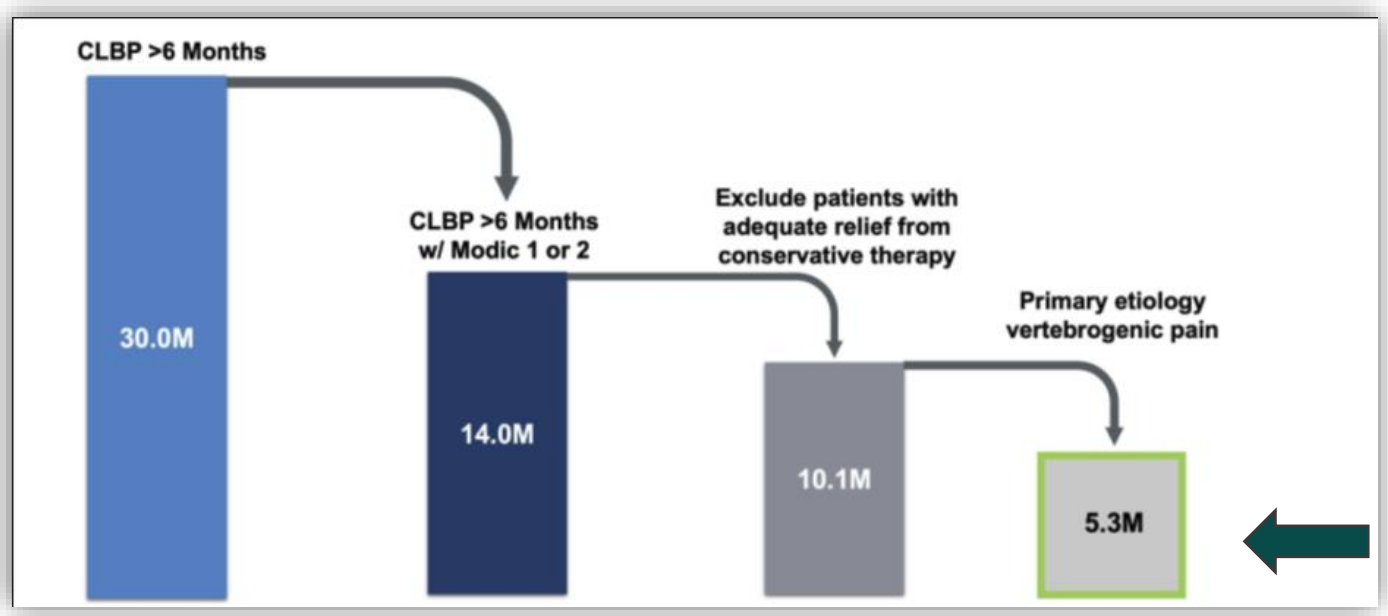


The level of willingness to adopt and fund an innovative technology is inversely correlated to the patient volume of the indication and price of the technology

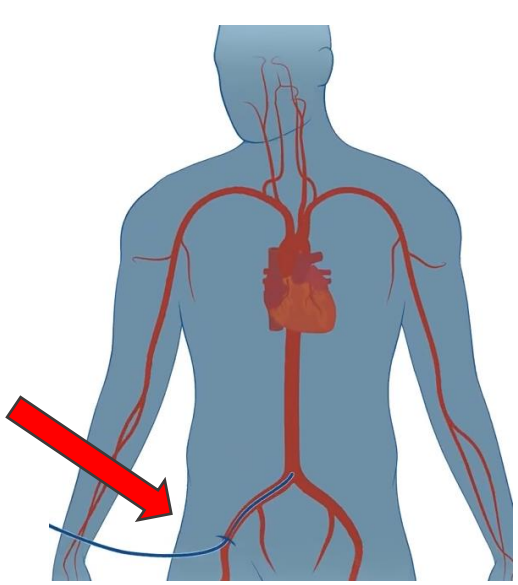
Example of target population identification
Technology to treat chronic lower back pain

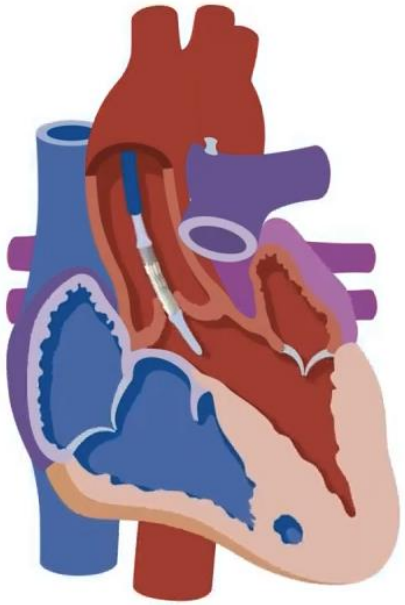
Further elements that may narrow down the initial target patient population:

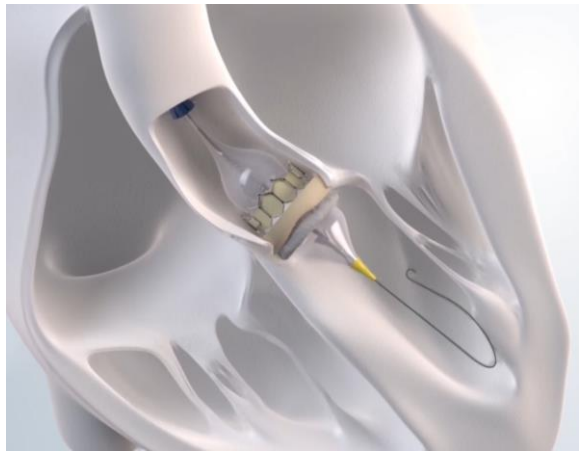
- SoC patient treatment pathway: Patient referral, place in treatment pathway (1st line, 2nd line), need for specific imaging in diagnostic work up
- Patient access to the technology: Clinical stakeholder by country, physician training, availability of the technology

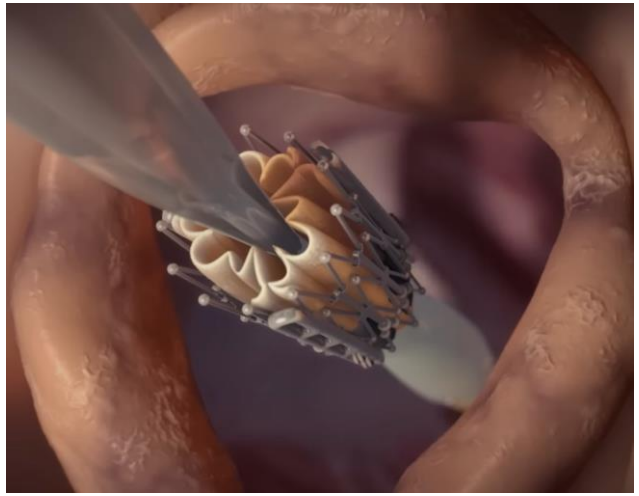


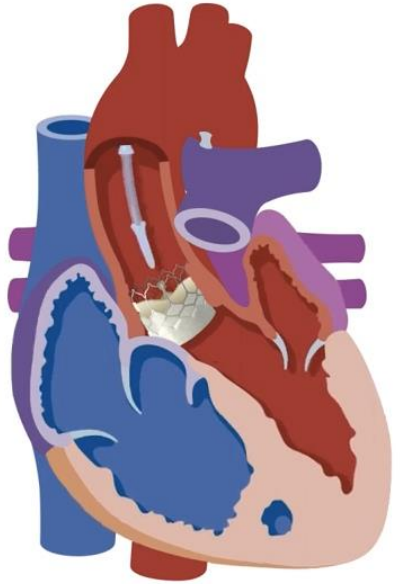
TAVR procedure steps











Market Access Strategy Development

- Steps and strategic assessment stages: Target Indication

Market Access Steps
Question: Market access challenges depend on the objectives set out for the technology: what are the objectives for your technology?

Establish initial utilisation

- **Identify the target indication / setting of care / type of provider**
- **Establish reimbursement mechanism and payer acceptance**
  Identify if a formal change is required in the system
  Remove formal hurdles

Grow to Target Indication

- **Increase the utilisation**

  Convince hospitals / clinicians about the value to adopt your technology

Grow share of use within current / evolving utilisation

- **Increase the market share within an established / evolving utilisation**

  Use clinical and economic evidence, tools and activities

Market Access Steps
Step I of a strategic assessment focuses on the external market access environment

Patient access to Care

- Complete or partial coverage?
- **Setting of care?**
- Role / strength of patient associations?

Reimbursement / Funding mechanisms

- Funding mechanism?
- **Is coding linked to hospital financing?**
- Process and timeline for new coding?
- Innovation funding available / needed?
- Pass-through / supplemental or add-on payments available?

Reimbursement / Funding Approval Pathways

- Centralized or decentralized approval?
- Frequency of updates and data required?
- Transparency of process?
- **Role and use of Health Technology Assessments?**

Step 1 assessment objectives

- Understand a market´s unique characteristics and options available
- Identify the main stakeholders IN EACH MARKET and their interaction

AVANIA

Market Access Steps
Step 2 of a strategic assessment focusses at micro level on the characteristics of a technology and how it fits in the market

External Device/Procedure factors

- Therapy = key focus?
- Level of coverage?
- **Physician support / training required?**
- Require **change in treatment pathways / organization?**
- Role of clinical guidelines?

Internal Device/Procedure factors

- Clinical value proposition?
- Economic impact; cost–Benefit; **cost effectiveness**?
- **Addresses unmet needs?**
- Competitive advantage?
- **Clinical value proposition in relation to price?**

Step 2 assessment objectives

- Evaluation of external factors that can impact support
- Understand and **VALIDATE** the core clinical and economic value proposition **IN EACH MARKET**

AVANIA

Market Access Tools

Clinical and health economic evidence

Health technology assessments

Clinical guidelines

AVANIA

Market Access Tools

Clinical and health economic evidence

AVANIA

The Regulatory / Reimbursement Dilemma

Uncertainty about the incremental value is the main reason for the gap between CE marking and adoption. Only the right type of evidence can mitigate this gap.

Risk Assessment Criteria for Regulatory Approval	Risk Assessment Criteria for Market Access and Reimbursement
1. Is the product Safe?	1. What is the unmet need?
	2. How is your solution better than the alternates?
	3. What is the history and cost of those alternatives?
2. Is the product technically sound (performance tested)?	4. What am I currently paying?
	5. What is the selling price of your device cost and why is it worth it?
	6. Can I afford your device?
3. Are there any additional post licencing requirements?	7. What are the consequences of NOT funding this?
	8. Which patients should get access?

CE mark (regulatory) evidence determines acceptability,
Reimbursement determines value.
This is consistent across all health systems

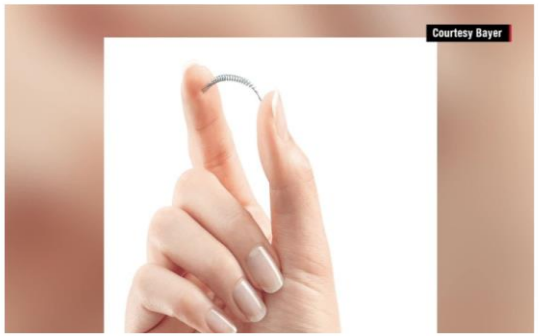
AVANIA

Trend towards post market evidence collection was triggered by a variety of high profile faulty medical devices

Bayer to stop selling Essure birth control device in US

By Susan Scutti, CNN

Updated 2102 GMT (0502 HKT) July 20, 2018



2015: Essure sterilization method under fire 01:54

PIP breast implant scandal: Here's what you need to know

HEALTH | WORLD | FRANCE | BREAST IMPLANTS | Thursday 20 May 2021, 4:04pm

Women who had received the faulty breast implants demanded compensation
Credit: PA

The victims of defective breast implants made by a French company should receive financial compensation, ruled a Paris appeal court in France. The case involved around 2,700 women, 540 of whom were Britons.

Thursday's ruling, which might not be final and could go to another higher court, was announced by France-based association PIPA, which represents victims.

SA lawyers launch medical class action against use of pelvic mesh device

Two legal firms are taking five companies to court over the device which has caused suffering among women worldwide

BL PREMIUM

29 AUGUST 2021 - 17:17 *by* ALISTAIR ANDERSON

A group of lawyers are launching a class action over defective trans-vaginal mesh devices which have caused women worldwide to suffer.

The decision to launch the class action follows a legal victory in Australia two years ago...

UK breast implant victims welcome compensation ruling

UK News | Published: Jun 3, 2021

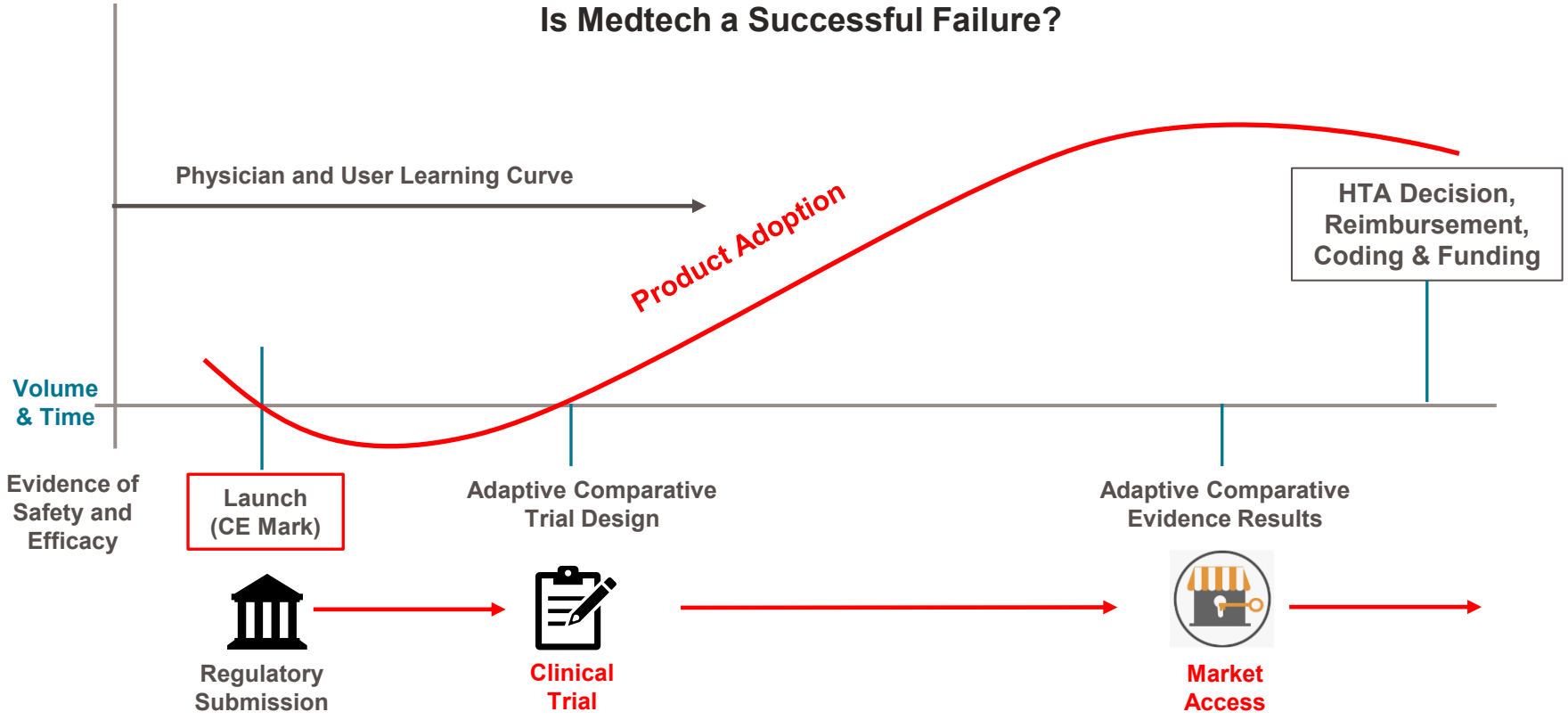
A French appeal court said German company TUV Rheinland committed negligence by certifying the PIP implants as safe.

British women affected by the PIP breast implant scandal have welcomed the ruling of a French court that around 2,700 victims are entitled to compensation.

An appeal court said German company TUV Rheinland committed negligence by certifying the implants as safe.

Thursday's ruling, which might not be final and could go to a higher court, was announced by France-based association PIPA, which represents victims.

Even breakthrough innovations have had issues to become standard of care or take far too long to reach broad adoption, due to uncertaintly.



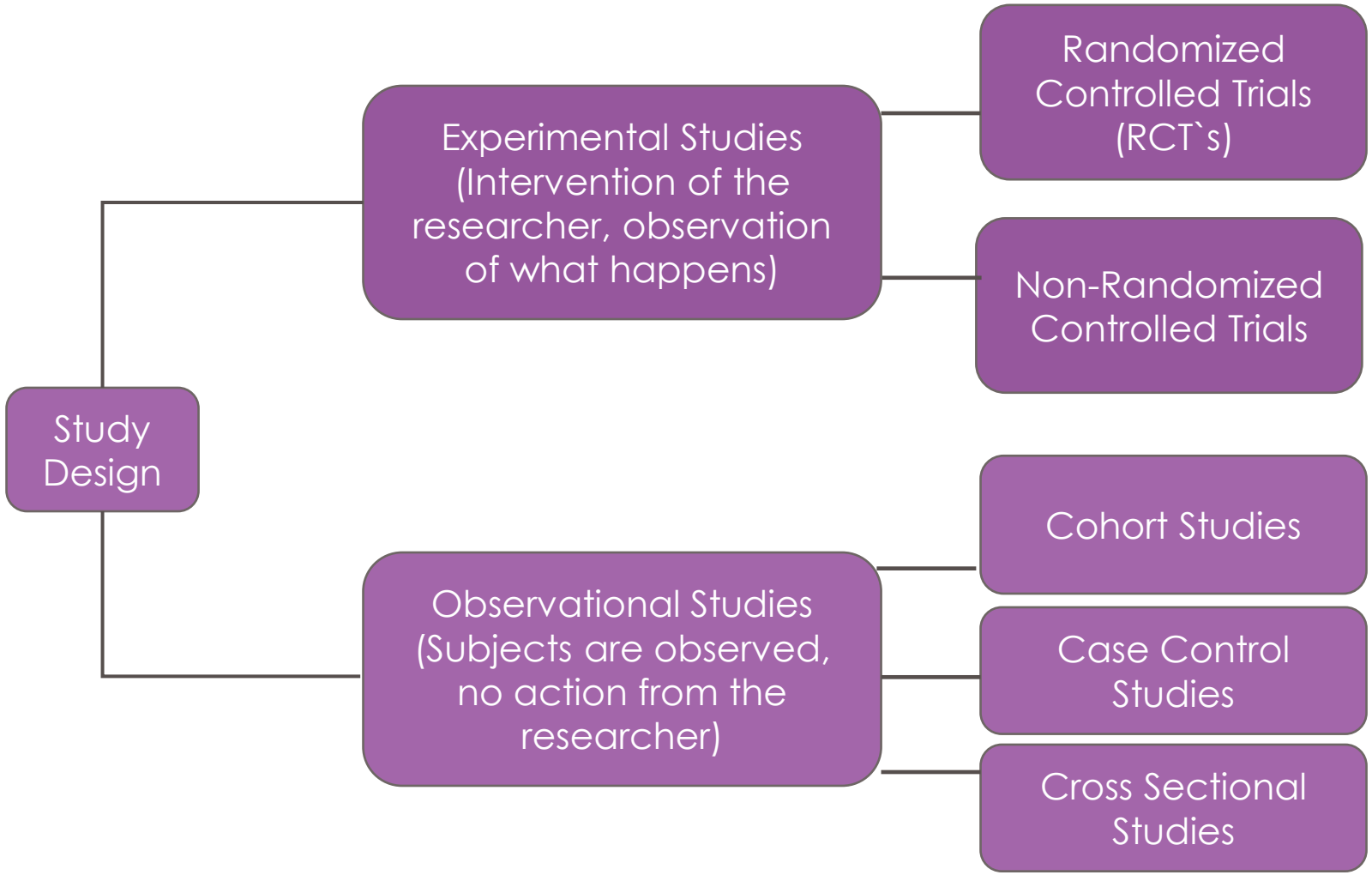
The medtech industry filed 15,300 patents worldwide in 2021 worldwide,

Equal to 8,1% of total patents filed

55% of medtech patents are granted vs. 33% of pharma patents

Clinical and Health Economic Evidence
Payers reduce uncertainty by demanding evidence to inform market access and reimbursement decisions

Clinical Evidence
Types of studies to collect clinical evidence



Health Economic Evidence
Types of studies to collect health economic evidence

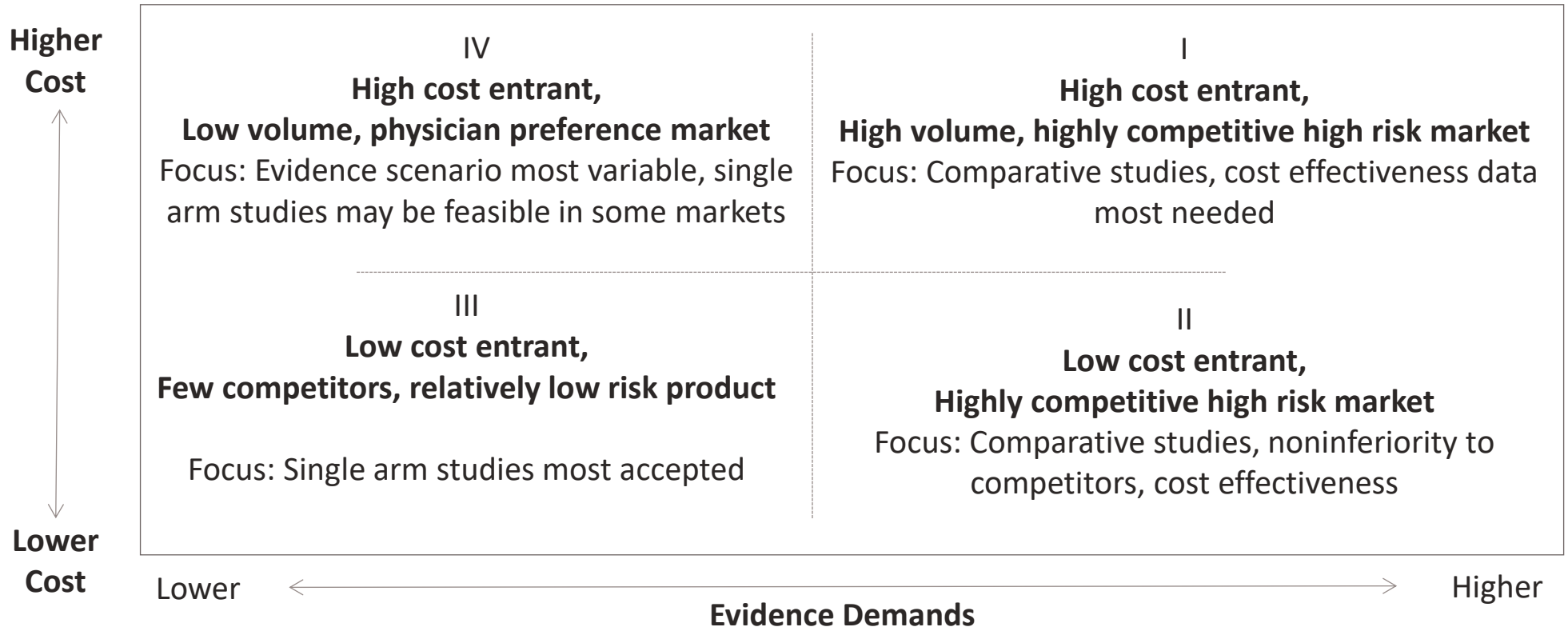
Analysis Type	Outcomes	Costs	Remark
Cost Benefit Analysis (CBA)	Transformed and measured in monetary units	Expressed in money units	Expressing outcomes (the price of a human life) is quite challenging
Cost Effectiveness Analysis (CEA)	Expressed in natural units (number of life years saved, incidence of disease, etc)	Expressed in money units	The most common analysis
Cost Utility Analysis (CUA)	Expressed in QALY0s	Expressed in money units	Special type of CEA
Cost consequence analysis (CCA)	Listed in natural units	Listed in money units	Outcomes and costs are reported separately, no ratio

* Also exists: Cost minimization analysis, budget impact analysis

AVANIA

Question: The demand for evidence varies depending on the cost impact of the technology and competitive landscape: What evidence will you be required to provide in the target market?

What scenarios drive demand for evidence?

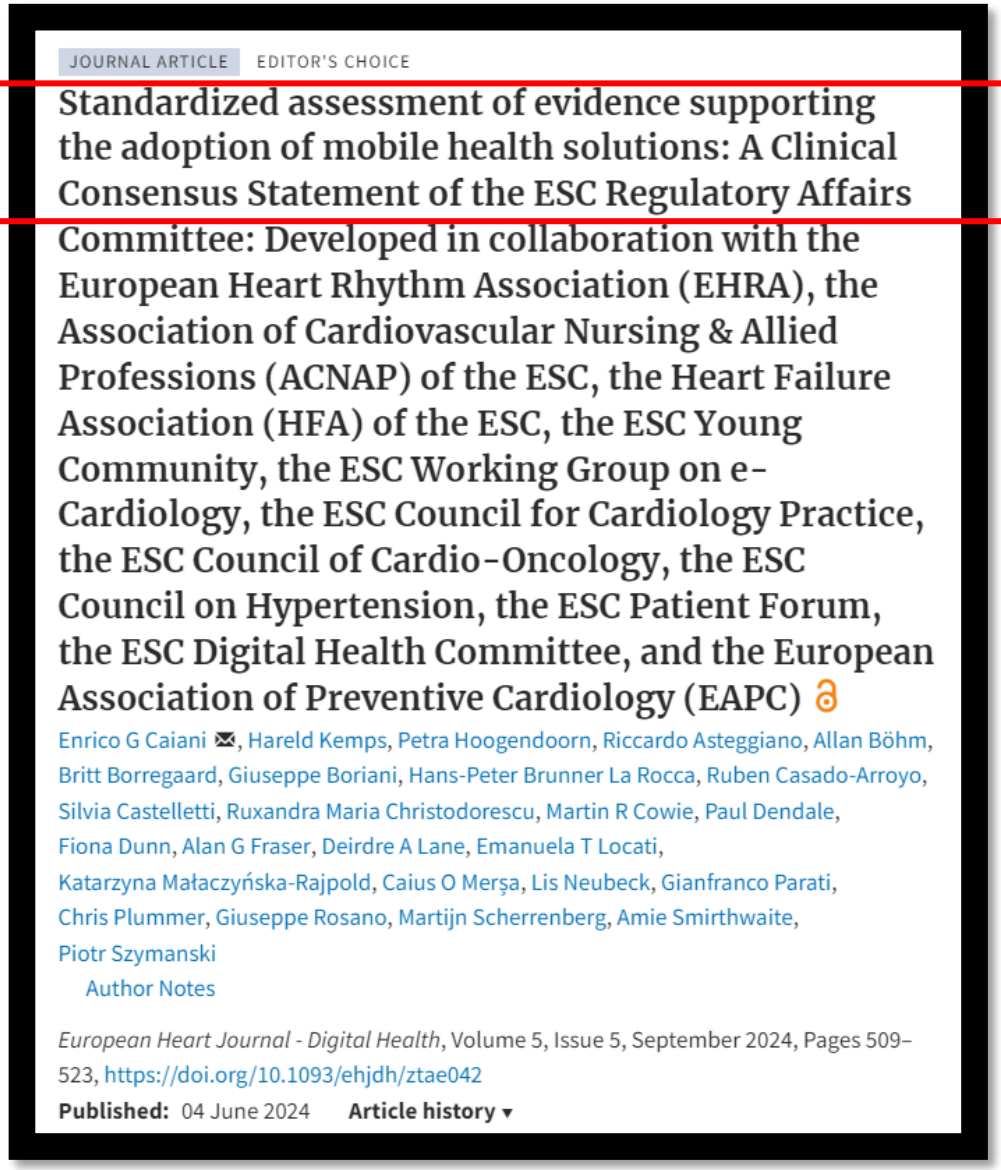


General factors to bear in mind

Price relative to competitors

Patient volume and total cost of treatment

Societies may publish recommendations on the evidence required to support the adoption and reimbursement of medical technologies



JOURNAL ARTICLE EDITOR'S CHOICE

Standardized assessment of evidence supporting the adoption of mobile health solutions: A Clinical Consensus Statement of the ESC Regulatory Affairs Committee: Developed in collaboration with the European Heart Rhythm Association (EHRA), the Association of Cardiovascular Nursing & Allied Professions (ACNAP) of the ESC, the Heart Failure Association (HFA) of the ESC, the ESC Young Community, the ESC Working Group on e-Cardiology, the ESC Council for Cardiology Practice, the ESC Council of Cardio-Oncology, the ESC Council on Hypertension, the ESC Patient Forum, the ESC Digital Health Committee, and the European Association of Preventive Cardiology (EAPC)

Enrico G Caiani, Hareld Kemps, Petra Hoogendoorn, Riccardo Asteggiano, Allan Böhm, Britt Borregaard, Giuseppe Boriani, Hans-Peter Brunner La Rocca, Ruben Casado-Arroyo, Silvia Castelletti, Ruxandra Maria Christodorescu, Martin R Cowie, Paul Dendale, Fiona Dunn, Alan G Fraser, Deirdre A Lane, Emanuela T Locati, Katarzyna Małaczyńska-Rajpold, Caius O Merşa, Lis Neubeck, Gianfranco Parati, Chris Plummer, Giuseppe Rosano, Martijn Scherrenberg, Amie Smirthwaite, Piotr Szymanski

Author Notes

European Heart Journal - Digital Health, Volume 5, Issue 5, September 2024, Pages 509–523, https://doi.org/10.1093/ehjdh/ztae042

Published: 04 June 2024 **Article history** ▾

Reflections on Clinical and Health Economic Evidence

Questions to ask yourself <u>for each market</u>

1. What is the core clinical and economic value propostion of your device?
    - Versus competitors and standard of care?

2. What evidence on clinical outcomes and/ or economic evidence will you require to back up the core value proposition(s) for clinicians to adopt your technology?
    - What clinical and economic evidence will likely be required by further stakeholders to support coverage and reimbursement?

Market Access Tools

Health Technology Assessments: What are HTA's

AVANIA

Published evidence is the base for Health Technology Assessments used to inform national / local pricing and reimbursement decisions and evidence based clinical guidelines

What is HTA?

Health Technology Assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. INAHTA

The **purpose** is to inform decision-makers in order to promote an equitable, efficient, and high-quality health system.

HTA can cover both clinical and non-clinical aspects of a healthcare technology, which manifest in different domains.

HTA domains

Clinical domains:

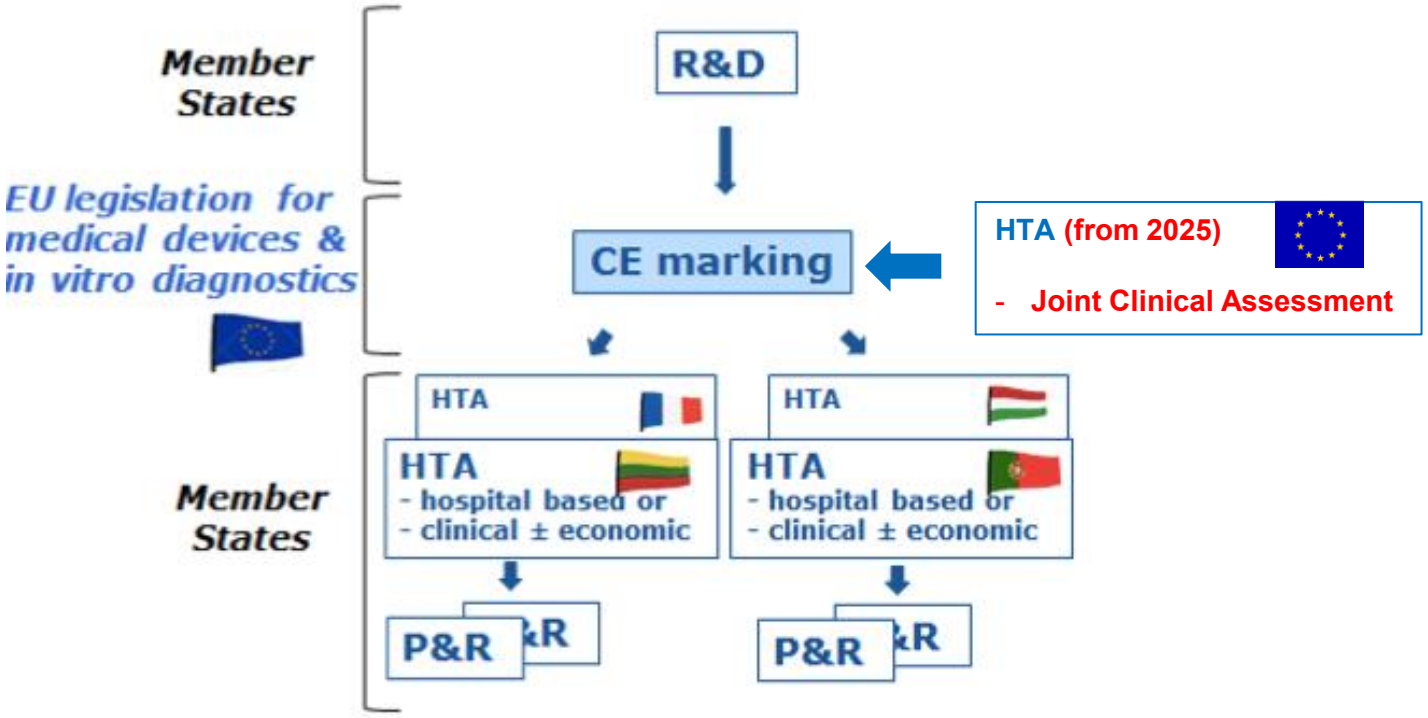
- Health problems and current use of health technologies.
- Description of health technology under assessment.
- Relative clinical effectiveness.
- Relative safety

Non-clinical domains

- Economic evaluation
- Ethical aspects
- Organisational aspects
- Social aspects
- Legal aspects

HTA: Health technology assessments are carried out at every level of decision making: European (from 2025), national, regional and local

HTA in the context of market access pathways for medical technologies



HTA's contribute to the sustainability of health systems by providing scientific evidence / input for local pricing and procurement processes for medical devices

HTA: Multiple national and regional HTA agencies exist across Europe

European HTA Map

Switzerland:

SNHTA Swiss Network for Health Technology Assessment

Spain:

grouped into the Spanish Network of Health Technology and Services Evaluation

Agency	Region
AETS - ISCIII	National
UETS-ALE	Madrid
AETSA	Andalucia
Avalia-T	Galicia
AIAQS / AATRM	Cataluña
SESC	Canary Islands
OSTEBA	Basque Countries
IACS	Aragon

AVANIA

HTA: In Europe, national and regional HTA agencies are coordinated through EUnetHTA

European HTA Projects:

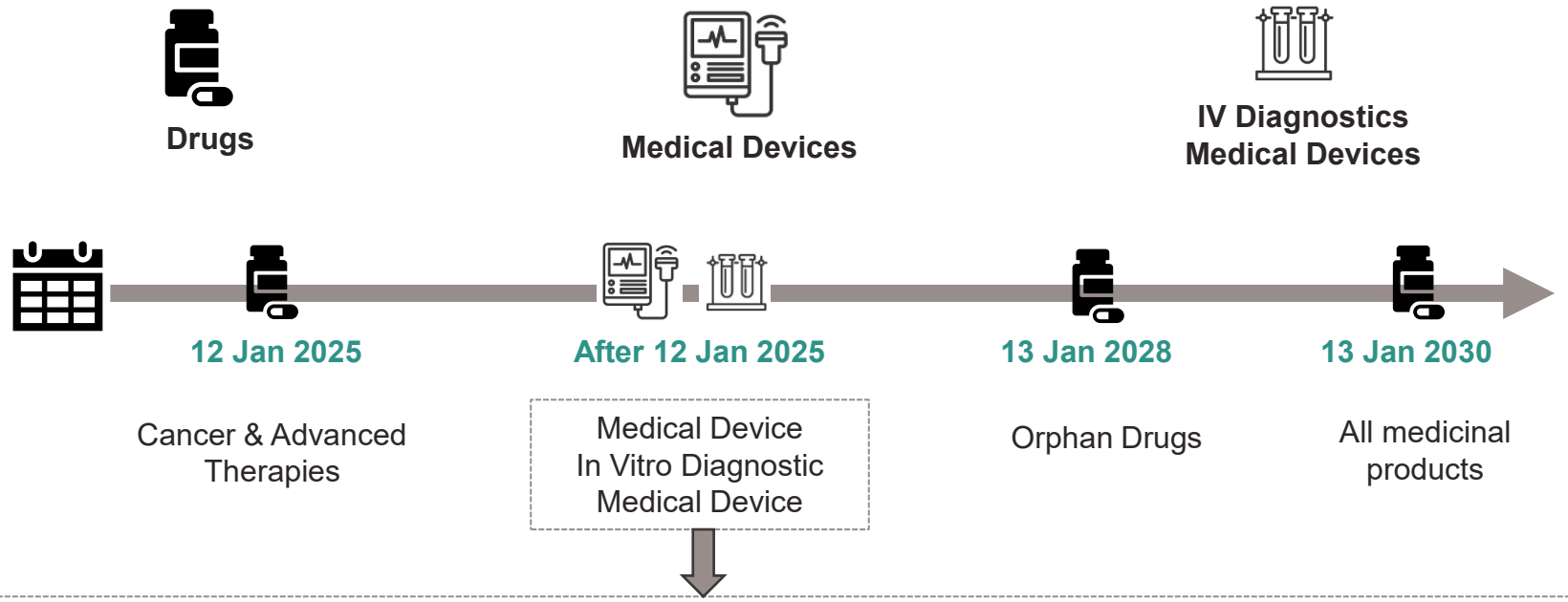
HTACG: Subgroup for Joint Clinical Assessments

EUnetHTA Network:

- Joint Clinical Assessment
- FP-7 Research

European Joint Clinical Assessments from 2025 are focused on evaluating the clinical domains only of some medical technologies, to enhance availability of innovation

Health Technologies affected by Joint Assessment



Selection of high-risk implantable MD classified as Class IIb or III and IVDs class D for which relevant expert panels have provided a scientific opinion in framework of clinical evaluation consultation procedure of clinical domains only

Selected for Joint Clinical Assessment based on one or more of the following criteria:

- Unmet clinical needs
- First in class
- Potential impact on patients, public health or healthcare systems
- Incorporation of software using artificial intelligence, machine learning technologies or algorithms
- Significant cross-border dimension
- Major European Union added value

AVANIA

Market Access Tools

Health Technology Assessments: The implication of HTA's on Market Access

AVANIA

HTA: National and regional level HTA organizations issue HTA's to guide coverage, payment and adoption of appropriate treatments.

Swedish MTP Council recommended delaying the introduction of robotic surgery for knee, hip, and spine

27 Jun 2023

On June 13, 2023, the Swedish Medical Technologies Product (MTP) Council recommended that all regions delay the introduction of robotic systems for knee, hip, and spine surgery until they have been evaluated as part of the Orderly introduction framework. For now, MTP Council recommends robotic systems in these indications only to be used in the context of research.

Rapid HTAs of two medical devices released in Tuscany

23 Jun 2023

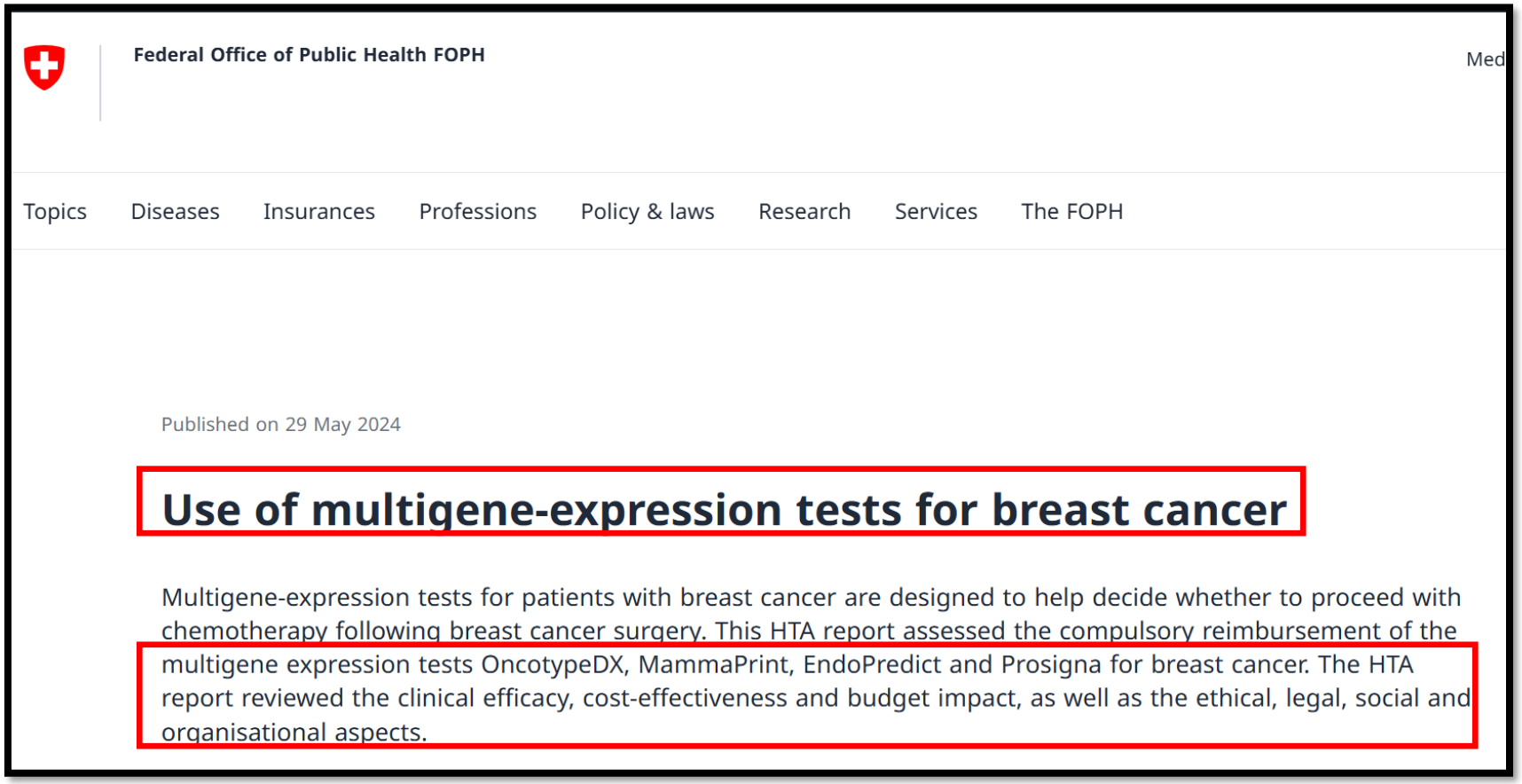
The HTA body of the Tuscany Regional Healthcare issues three types of documents: full HTA reports, rapid HTA reports, and motivational forms. With regional decree 11957 of June 07, 2023, Tuscany Regional Healthcare has published assessments of two medical devices in the cardiovascular and spine areas.

The following technologies have been assessed:

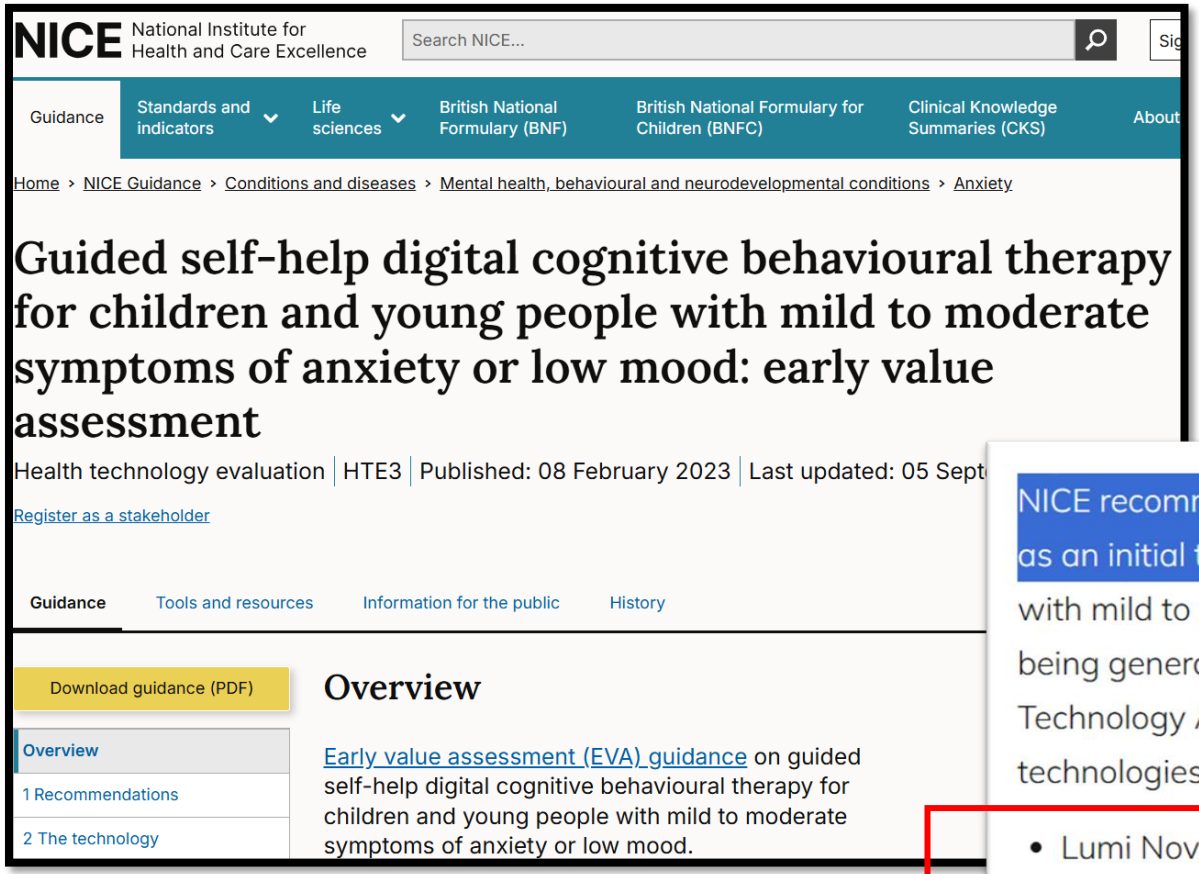
- Cobalt-chrome external stent Vest 2.0 by Vascular Graft Solution for patients undergoing a coronary artery bypass graft procedure for the treatment of severe arteriosclerotic coronary artery disease;
- Removable percutaneous interspinous fusion device QFusion by Techlamed for patients affected by neurogenic claudication due to symptomatic stenosis of the vertebral canal associated with instability and who are not candidates for open surgery due to contraindications or comorbidities.

AVANIA

HTA: In Switzerland, the Federal Office of Public Health uses HTA's to determine coverage of novel technologies or procedures



NICE conducted an evaluation and provided recommendations on digital cognitive behavioural therapy technologies for children

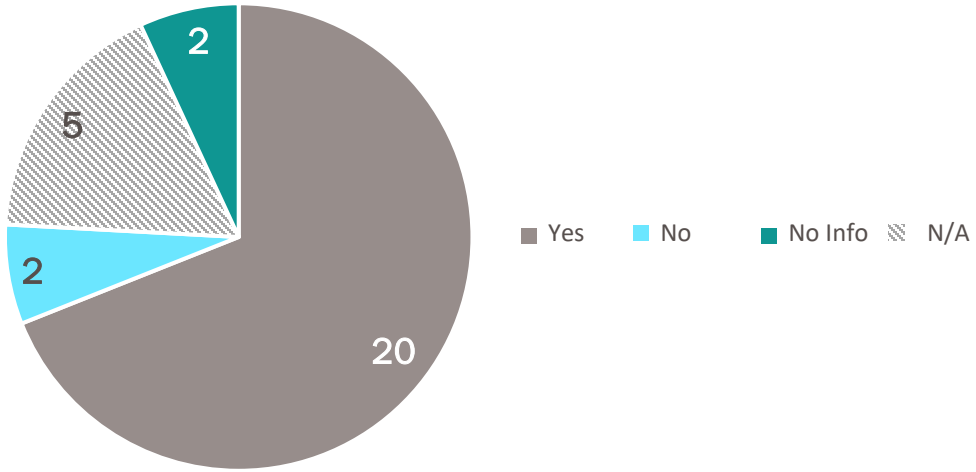


NICE recommended four guided self-help digital CBT technologies to be used as an initial treatment option for children and young people (aged 5 to 18) with mild to moderate symptoms of anxiety or low mood while evidence is being generated. These technologies can be used once they have Digital Technology Assessment Criteria (DTAC) approval from NHS England. The technologies are:

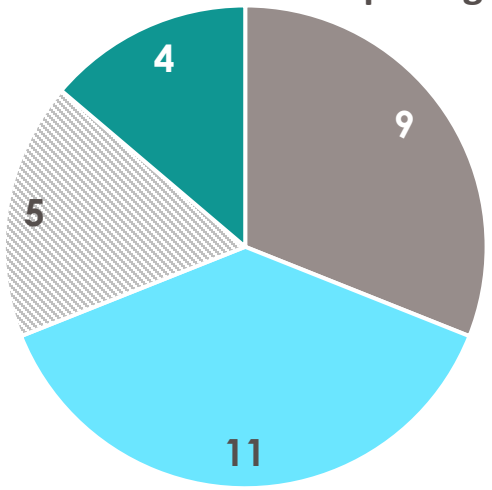
- Lumi Nova (by BfB labs);
- Online Social anxiety Cognitive therapy for Adolescents (by OSCA);
- Online Support and Intervention for child anxiety (by OSI);
- Space from anxiety for teens, space from the low mood for teens, space from low mood and anxiety for teens (by Silvercloud);

HTA's form an obligatory or advisory role in informing reimbursement and pricing decisions depending on the country: What is the case in your target market?

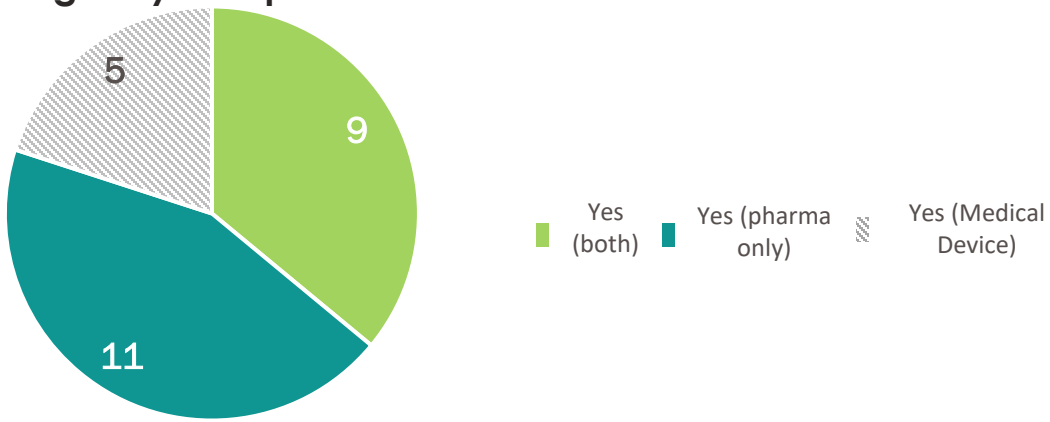
Number of countries where HTA's are used to inform reimbursement decisions



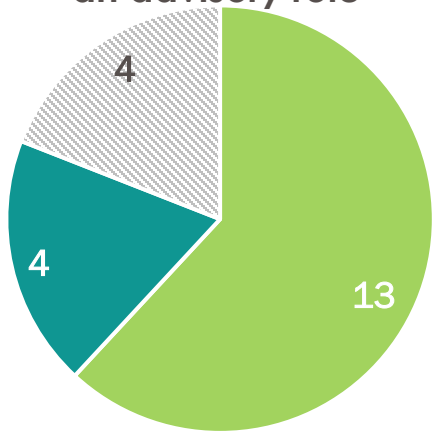
Number of countries where HTA's are used to inform Medtech pricing decisions



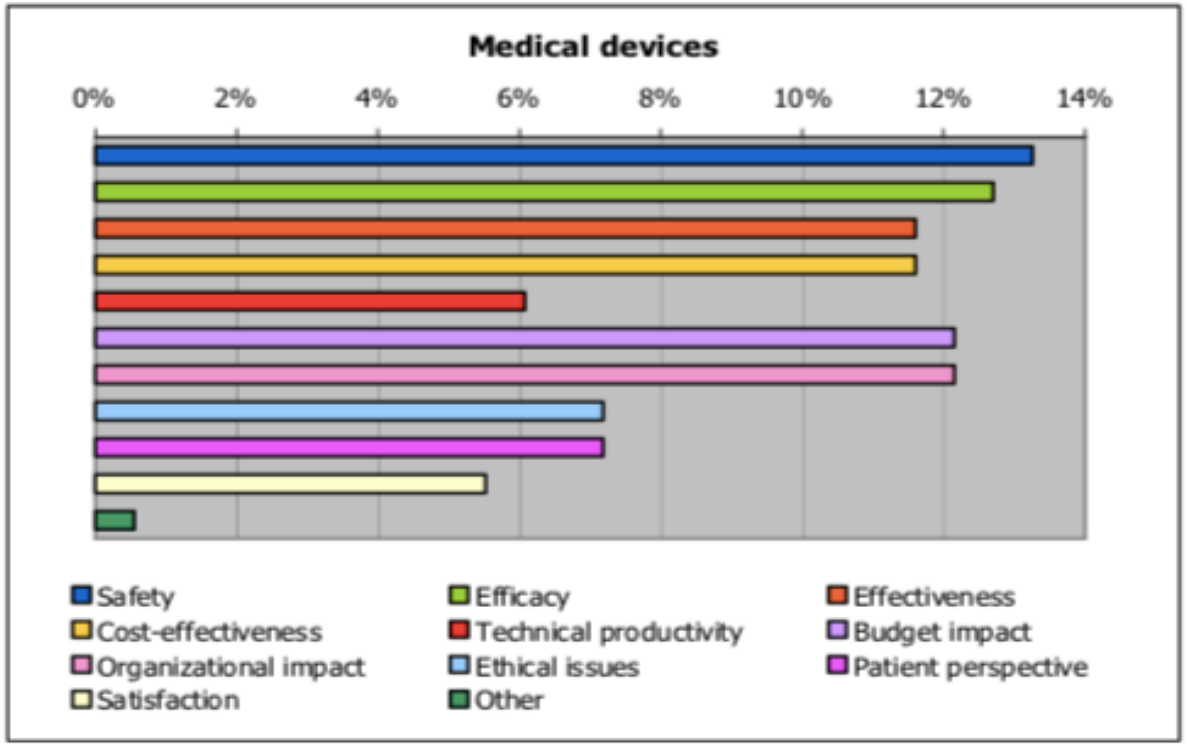
Number of countries where HTA's are of obligatory compliance



Number of countries where HTA's have an advisory role



HTA: Hospital based HTA's are frequently used for local decision making around the adoption of innnovations



- Hospital based HTA – "Mini HTA" allow hospital decision makers ol to assess and prioritize
  - Investment decisions
  - Improve clinical practice through innovation
  - Adapted to hospital clinical practice, comparators, organization of care
  - Uses hospital level data
  - Challenge Industry claims
- Most common dimensions: **safety, efficacy and (cost) effectiveness**
- Further key criteria: **budget impact and organisational impact**.
- **Technical productivity and patient satisfaction rank much lower.**

Health Technology Assessments Take Away's

1. Health technology assessments inform clinical and economic stakeholders take decisions around the coverage and adoption of medical technologies.

    - HTA's are always based on published clinical and health economic evidence

    - HTA's by some agencies can have a worldwide impact on technology coverage and adoption. Therefore voluntary engagement in a HTA should be carefully considered

2. HTA's can form an obligatory or advisory role in informing coverage, adoption and reimbursement, depending on the market.

3. From January 2025 European wide Joint Clinical Assessments will be performed on class IIb and class III devices that comply with specific criteria.

    - JCA's will focus only on 4 core domains.

    - Domains to be evaluated at local market level: Cost and economic effectiveness, Ethical, Organizational, Patient and Social as well as Legal aspects

Market Access Tools

Clinical Guidelines

AVANIA

Guidelines: Question: what do clinical guidelines say about your technology or the standard of care in the target market?

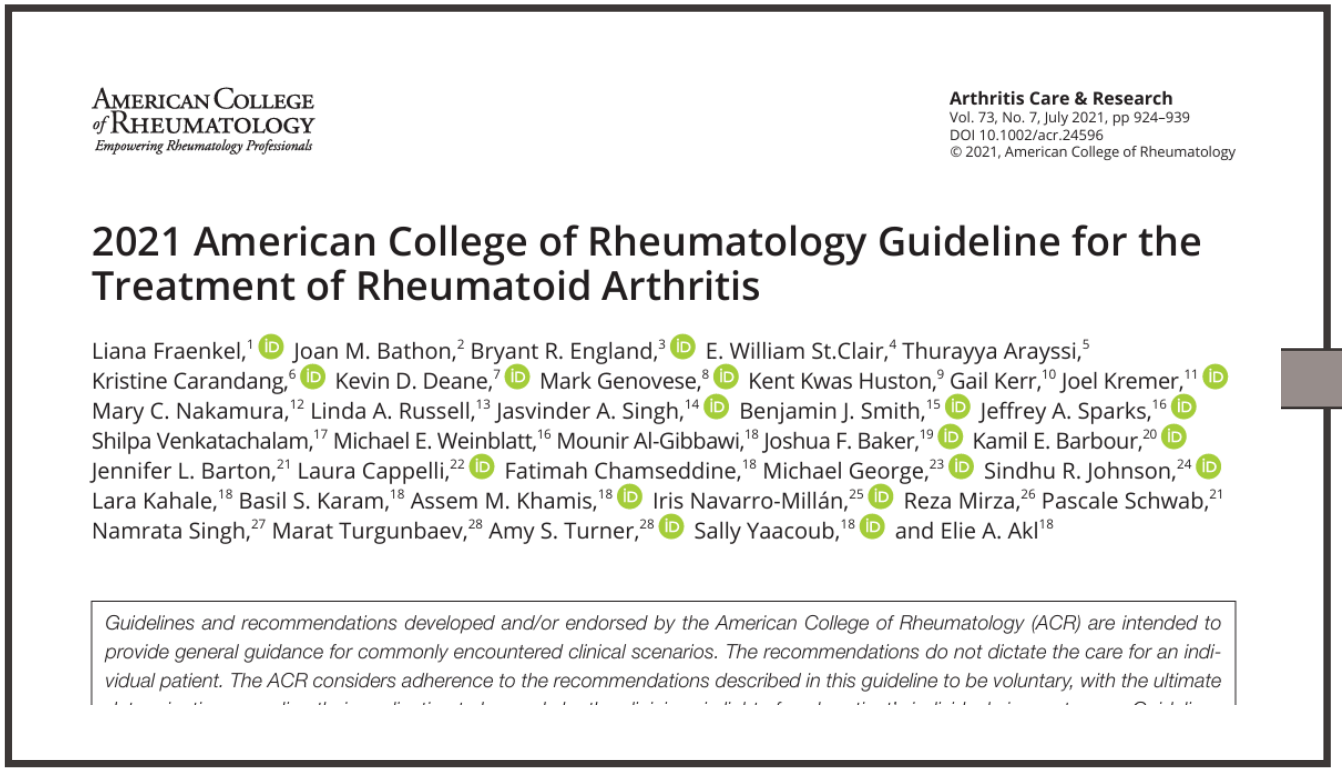
- Guidelines are not fixed protocols but are intended for health care professionals and providers to consider.

- They identify and describe generally recommended courses of intervention

Clinical Practice Guidelines	
What	Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances
Who	Specialist Societies / Public Administration / Care Providers

212

Guidelines: American guidelines are often considered in the development of European and local guideline driven care.



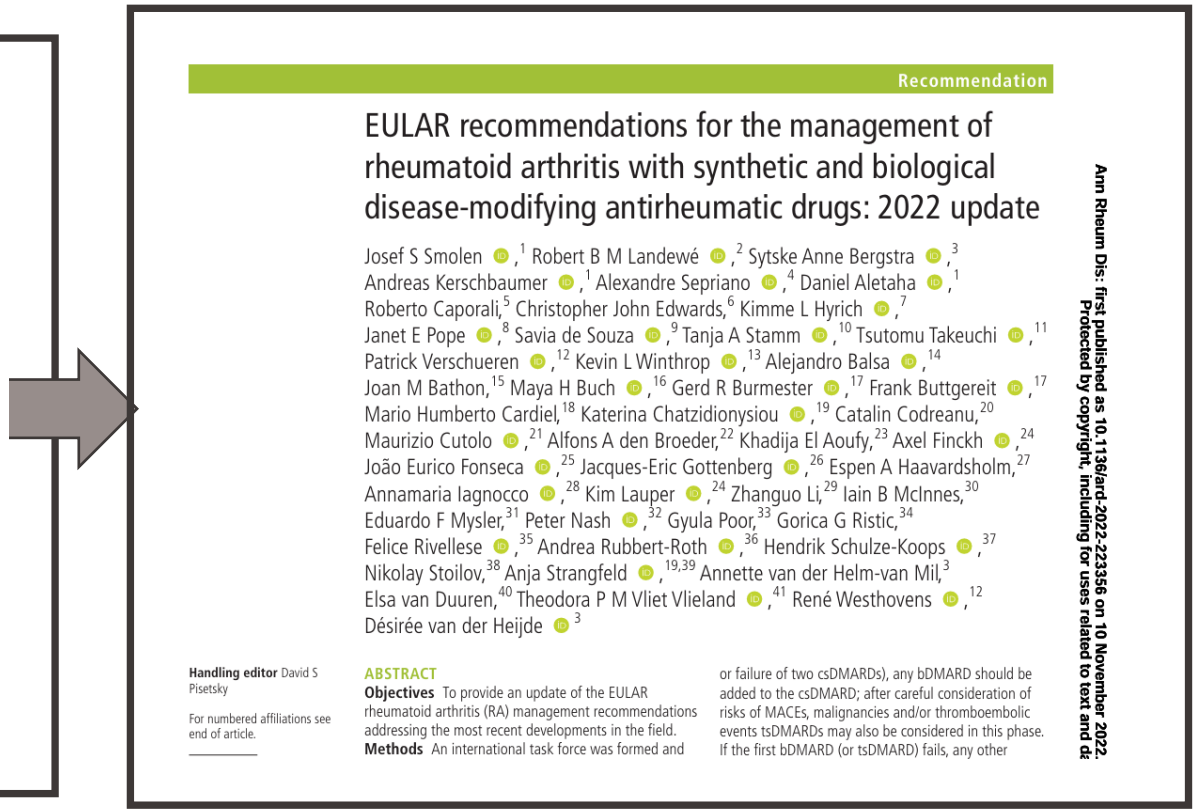
AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

Arthritis Care & Research
Vol. 73, No. 7, July 2021, pp 924–939
DOI 10.1002/acr.24596

2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis

Liana Fraenkel,[1] Joan M. Bathon,[2] Bryant R. England,[3] E. William St.Clair,[4] Thurayya Arayssi,[5] Kristine Carandang,[6] Kevin D. Deane,[7] Mark Genovese,[8] Kent Kwas Huston,[9] Gail Kerr,[10] Joel Kremer,[11] Mary C. Nakamura,[12] Linda A. Russell,[13] Jasvinder A. Singh,[14] Benjamin J. Smith,[15] Jeffrey A. Sparks,[16] Shilpa Venkatachalam,[17] Michael E. Weinblatt,[16] Mounir Al-Gibbawi,[18] Joshua F. Baker,[19] Kamil E. Barbour,[20] Jennifer L. Barton,[21] Laura Cappelli,[22] Fatimah Chamseddine,[18] Michael George,[23] Sindhu R. Johnson,[24] Lara Kahale,[18] Basil S. Karam,[18] Assem M. Khamis,[18] Iris Navarro-Millán,[25] Reza Mirza,[26] Pascale Schwab,[21] Namrata Singh,[27] Marat Turgunbaev,[28] Amy S. Turner,[28] Sally Yaacoub,[18] and Elie A. Akl[18]

Guidelines and recommendations developed and/or endorsed by the American College of Rheumatology (ACR) are intended to provide general guidance for commonly encountered clinical scenarios. The recommendations do not dictate the care for an individual patient. The ACR considers adherence to the recommendations described in this guideline to be voluntary, with the ultimate



Recommendation

EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update

Josef S Smolen ,[1] Robert B M Landewé ,[2] Sytske Anne Bergstra ,[3] Andreas Kerschbaumer ,[1] Alexandre Sepriano ,[4] Daniel Aletaha ,[1] Roberto Caporali,[5] Christopher John Edwards,[6] Kimme L Hyrich ,[7] Janet E Pope ,[8] Savia de Souza ,[9] Tanja A Stamm ,[10] Tsutomu Takeuchi ,[11] Patrick Verschueren ,[12] Kevin L Winthrop ,[13] Alejandro Balsa ,[14] Joan M Bathon,[15] Maya H Buch ,[16] Gerd R Burmester ,[17] Frank Buttgereit ,[17] Mario Humberto Cardiel,[18] Katerina Chatzidionysiou ,[19] Catalin Codreanu,[20] Maurizio Cutolo ,[21] Alfons A den Broeder,[22] Khadija El Aoufy,[23] Axel Finckh ,[24] João Eurico Fonseca ,[25] Jacques-Eric Gottenberg ,[26] Espen A Haavardsholm,[27] Annamaria Iagnocco ,[28] Kim Lauper ,[24] Zhanguo Li,[29] Iain B McInnes,[30] Eduardo F Mysler,[31] Peter Nash ,[32] Gyula Poor,[33] Gorica G Ristic,[34] Felice Rivellese ,[35] Andrea Rubbert-Roth ,[36] Hendrik Schulze-Koops ,[37] Nikolay Stoilov,[38] Anja Strangfeld ,[19,39] Annette van der Helm-van Mil,[3] Elsa van Duuren,[40] Theodora P M Vliet Vlieland ,[41] René Westhovens ,[12] Désirée van der Heijde [3]

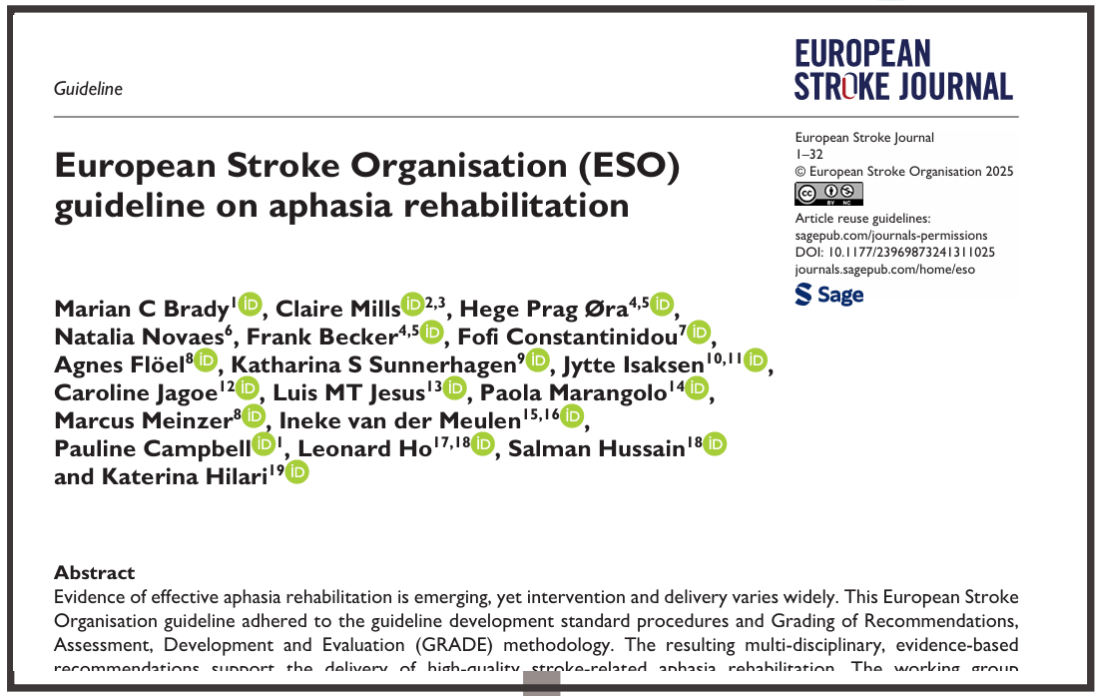
Handling editor David S Pisetsky

For numbered affiliations see end of article.

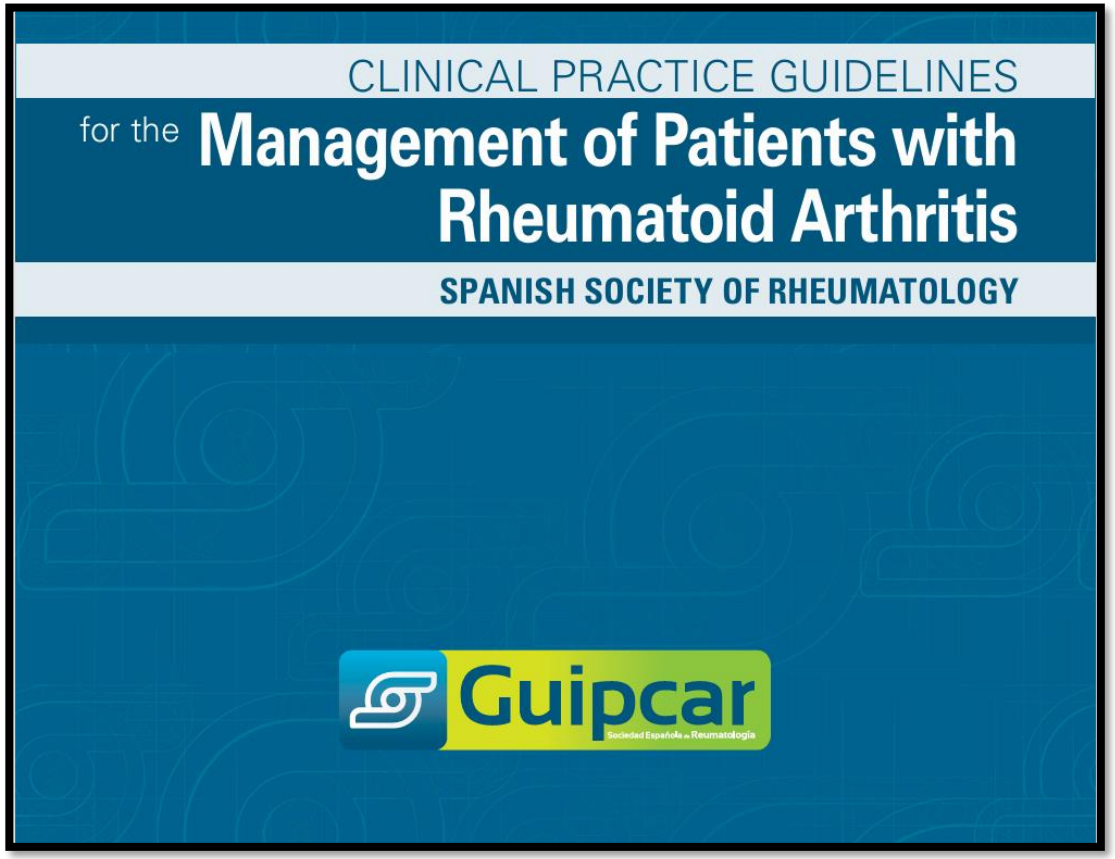
ABSTRACT
Objectives To provide an update of the EULAR rheumatoid arthritis (RA) management recommendations addressing the most recent developments in the field.
Methods An international task force was formed and

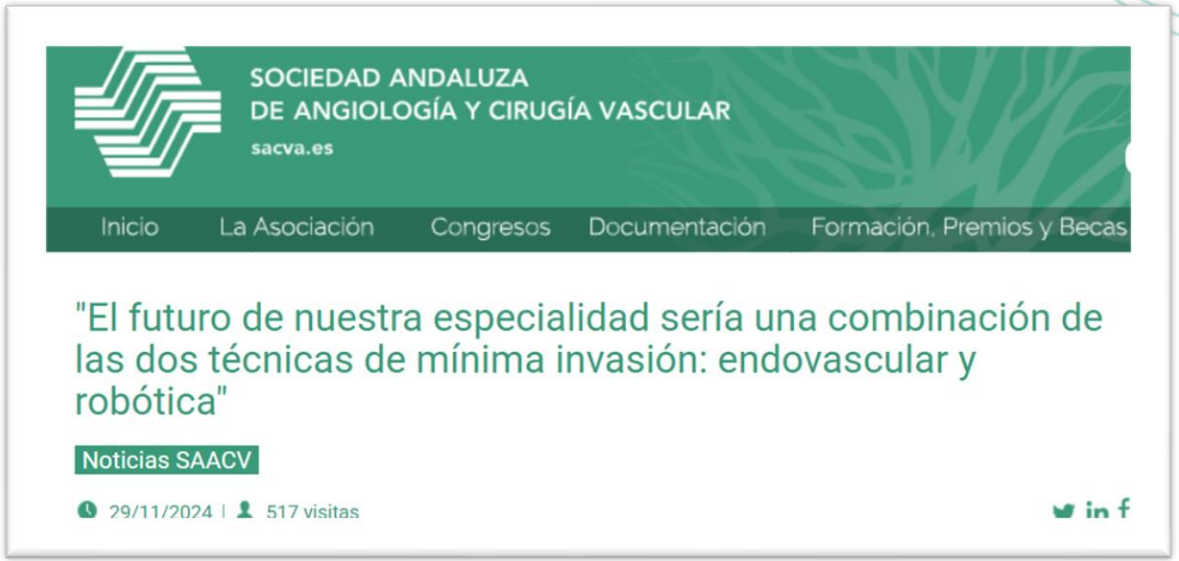
or failure of two csDMARDs), any bDMARD should be added to the csDMARD; after careful consideration of risks of MACEs, malignancies and/or thromboembolic events tsDMARDs may also be considered in this phase. If the first bDMARD (or tsDMARD) fails, any other

Guidelines: European guidelines often form the basis of local guideline driven care.



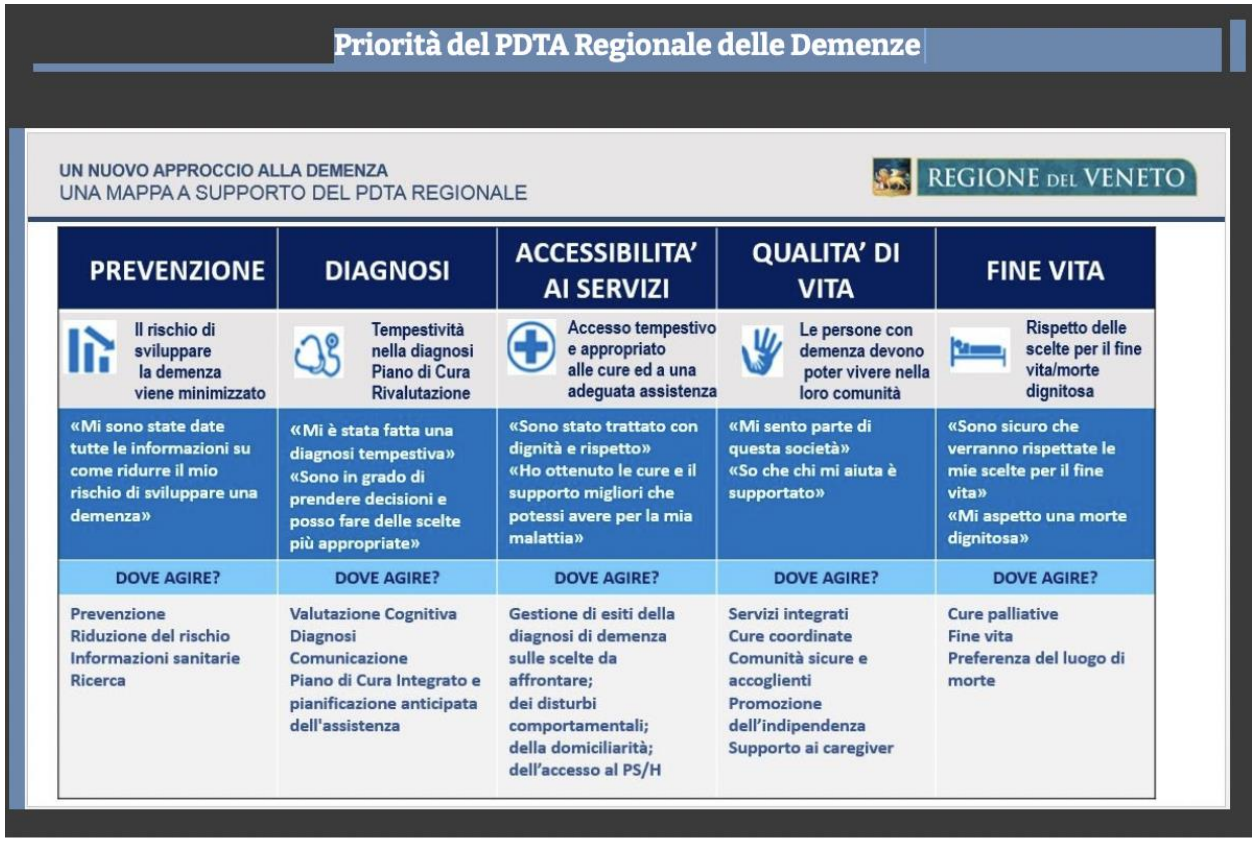
Guidelines: Specialist societies emit guidelines, position papers and quality standards that constitute standard of care.





220

Guidelines: Payer guidelines may indicate optimal organization of care and even indicate coding recommendations



Priorità del PDTA Regionale delle Demenze

UN NUOVO APPROCCIO ALLA DEMENZA
UNA MAPPA A SUPPORTO DEL PDTA REGIONALE

REGIONE DEL VENETO

PREVENZIONE	DIAGNOSI	ACCESSIBILITA' AI SERVIZI	QUALITA' DI VITA	FINE VITA
Il rischio di sviluppare la demenza viene minimizzato	Tempestività nella diagnosi Piano di Cura Rivalutazione	Accesso tempestivo e appropriato alle cure ed a una adeguata assistenza	Le persone con demenza devono poter vivere nella loro comunità	Rispetto delle scelte per il fine vita/morte dignitosa
«Mi sono state date tutte le informazioni su come ridurre il mio rischio di sviluppare una demenza»	«Mi è stata fatta una diagnosi tempestiva» «Sono in grado di prendere decisioni e posso fare delle scelte più appropriate»	«Sono stato trattato con dignità e rispetto» «Ho ottenuto le cure e il supporto migliori che potessi avere per la mia malattia»	«Mi sento parte di questa società» «So che chi mi aiuta è supportato»	«Sono sicuro che verranno rispettate le mie scelte per il fine vita» «Mi aspetto una morte dignitosa»
DOVE AGIRE?	DOVE AGIRE?	DOVE AGIRE?	DOVE AGIRE?	DOVE AGIRE?
Prevenzione Riduzione del rischio Informazioni sanitarie Ricerca	Valutazione Cognitiva Diagnosi Comunicazione Piano di Cura Integrato e pianificazione anticipata dell'assistenza	Gestione di esiti della diagnosi di demenza sulle scelte da affrontare; dei disturbi comportamentali; della domiciliarità; dell'accesso al PS/H	Servizi integrati Cure coordinate Comunità sicure e accoglienti Promozione dell'indipendenza Supporto ai caregiver	Cure palliative Fine vita Preferenza del luogo di morte

Il Percorso Diagnostico Terapeutico Assistenziale (PDTA) delle Demenze

3.2 Fase diagnostica

Obiettivi. Confermare o meno il sospetto diagnostico

Rete. Il paziente affetto da decadimento cognitivo si caratterizza per una complessità clinica che deriva dalla comorbilità[7] e dalla fragilità[8]. È quindi necessario elaborare un approccio clinico-diagnostico dedicato e multidisciplinare da parte dell'équipe multiprofessionale del CDCD.

Attività. La diagnosi di demenza spetta al medico specialista del CDCD supportato dalle competenze specifiche dello psicologo esperto in neuropsicologia. Il medico del CDCD prende in carico il paziente, formula un'ipotesi diagnostica, prescrive gli esami strumentali e condivide con lo psicologo l'ipotesi diagnostica. Lo specialista prescrive l'esame neuropsicologico e lo psicologo seleziona i test idonei (tabella 3).

Tabella 3. Codici del nomenclatore regionale relativi alla valutazione neuropsicologica completa

cod.94.09_9	Colloquio psicologico clinico
cod. 94.01.2_0	Somministrazione/ interpretazione di test per il deterioramento
cod.94.02.1_6	Test di attenzione
cod. 94.01.3	Valutazione monofunzionale; test semplice del linguaggio
cod. 94.08.1_0	Somministrazione/interpretazione test funzioni esecutive
cod. 94.08.2_0	Somministrazione/interpretazione abilità visuo spaziali
cod. 94.02.1_3	Somministrazione/interpretazione test della memoria

225

Clinical Guideline Take Away's

1. Clinical guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances and can be issued by specialist societies, payers and care providers.

    - They identify and describe generally recommended courses of intervention and strongly reference clinical evidence.

2. It is important to understand what guidelines say about a particular technology or procedure

    - **If a technology is recommended against in a clinical guideline it will likely impact decisions around coverage and adoption.**

        - Robust evidence, stakeholder support, time and resources will be required.

Strategic Stakeholder Sourcing

Strategic choice of stakeholders to support your market access strategy
Some sources of stakeholder identification: google is your friend

Physicians

- Authors / collaborators of - Specialist Society – Guidelines
- Members of specialist society organization
- Expert reviewers of HTA's
- Research project PI's (Pubmed)

Hospitals

- Reference centers: Specialist society guidelines / Patient society website / Ministry of Health
- High volume specialized centers (Registries)
- Articles in press

Public Healthcare (HTA's)

- National and European (EUnetHTA) health technology assessment agencies

Patients

- Relevant patient societies

Private Payers

- Top insurance companies + smaller insurance companies!

Stakeholders: Authors of specialist guidelines

Relevant KOL's and hospitals!! (for evidence generation and market access upport)

Guideline

EUROPEAN STROKE JOURNAL

European Stroke Journal
1–32
© European Stroke Organisation 2025

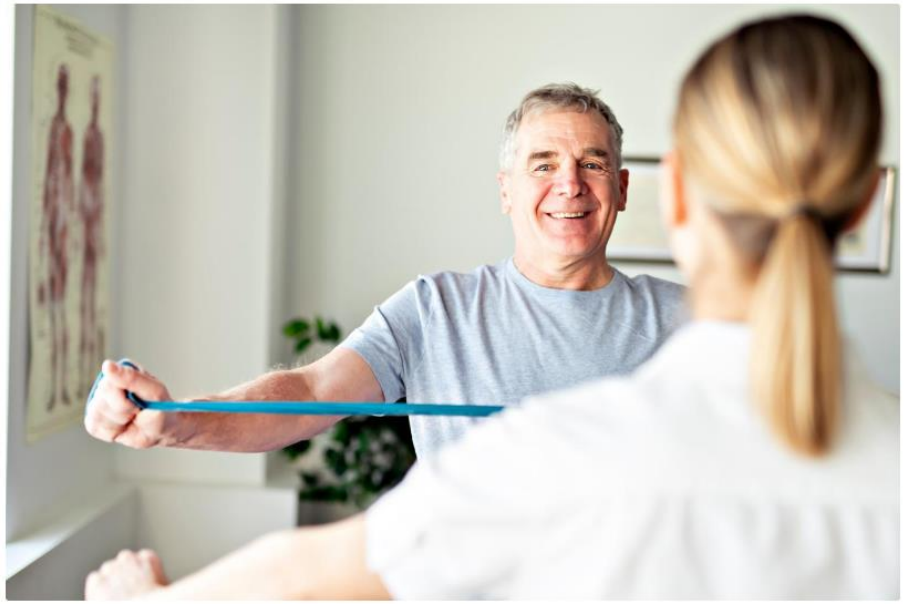
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/23969873241311025

European Stroke Organisation (ESO) guideline on aphasia rehabilitation

Marian C Brady[1], Claire Mills[2,3], Hege Prag Øra[4,5], Natalia Novaes[6], Frank Becker[4,5], Fofi Constantinidou[7], Agnes Flöel[8], Katharina S Sunnerhagen[9], Jytte Isaksen[10,11], Caroline Jagoe[12], Luis MT Jesus[13], Paola Marangolo[14], Marcus Meinzer[8], Ineke van der Meulen[15,16], Pauline Campbell[1], Leonard Ho[17,18], Salman Hussain[18] and Katerina Hilari[19]

Stakeholders
PI's in local research studies

ZonMw Financiering vinden Onderwerpen Actualiteit Over ZonMw



Het IIIe programma Revalidatieonderzoek concentreert zich op onderzoek naar het effect van revalidatie-interventies vanuit het perspectief van de patiënt.

Aanleiding

In 1997 verscheen het RGO Advies Revalidatieonderzoek; stimulatie van revalidatieonderzoek en inbedding van revalidatieonderzoek in medische faculteiten in Nederland. De conclusie was dat ontwikkelingen binnen het revalidatieonderzoek versnipperd plaatsvonden en gestreefd moest worden naar meer afstemming en coördinatie van onderzoek. De kwaliteit van het onderzoek was onvoldoende en de inbedding in de universitaire centra was te beperkt.

Revalidatie

Revalidatiegeneeskunde (VRA)

Kenmerken

Status: Afgerond

Budget: € 2.632.000

Looptijd: 100%

2013 2017

Vervolg op programma:

Revalidatieonderzoeksprogramma II

Subsidies

Bekijk alle open en gesloten subsidies van dit programma.

Projecten

Bekijk de projecten van dit programma.

Contact

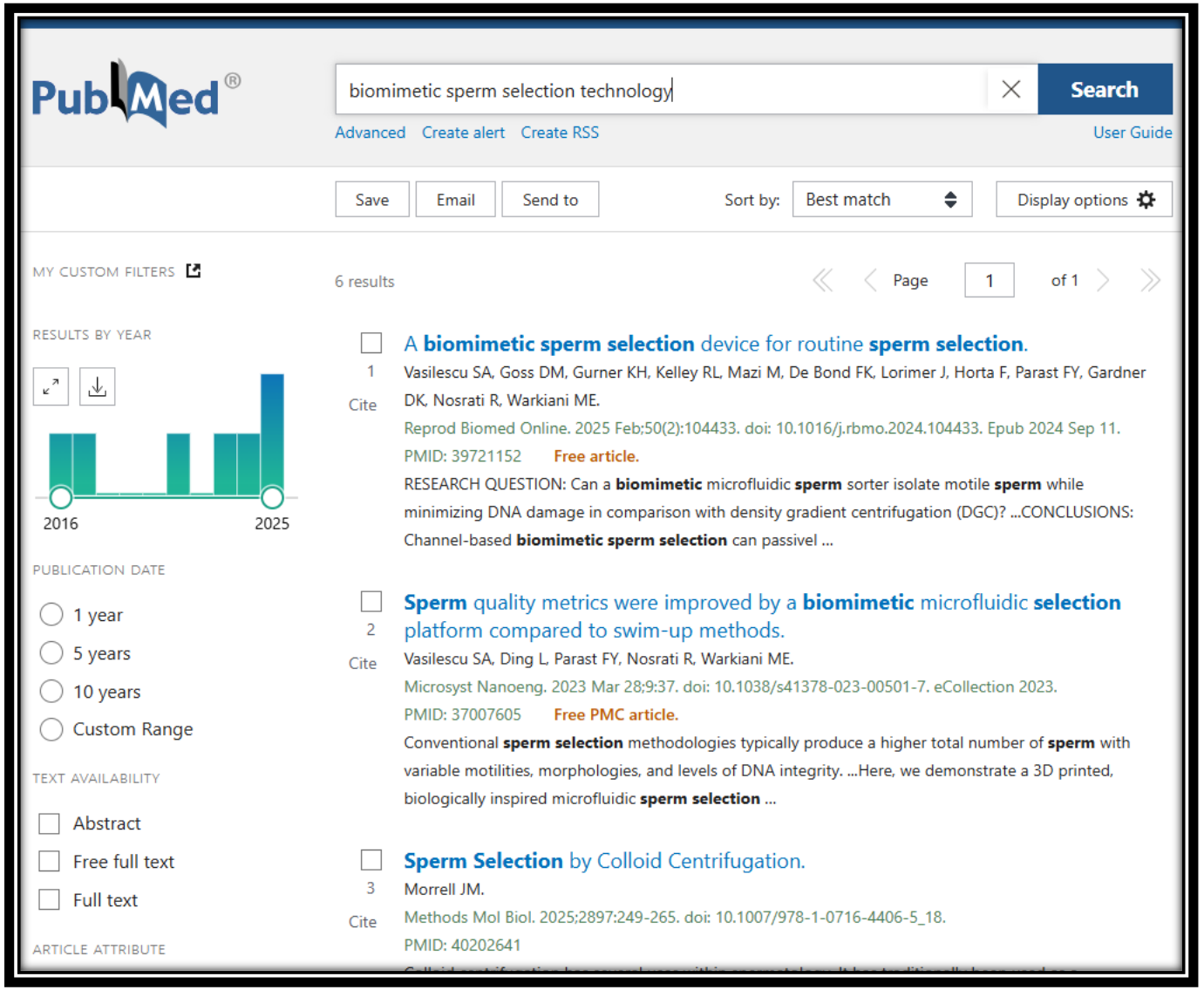
Martijn van Costa

Programmacoördinator

31 70 349 52 45

costa@zonmw.nl

Stakeholders
Authors of scientific publications (PubMed)



Stakeholders
Reference centers for specific disease or patient populations or high volume centers participating in registries

INFN Istituto Nazionale di Fisica Nucleare
Servizio Sanitario Regionale Emilia-Romagna Policlinico di Sant'Orsola
Sacro Cuore Don Calabria IRCCS
IMN Istituto di Ricerche Farmacologiche Mario Negri IRCCS
I.R.C.C.S. Ospedale San Raffaele Gruppo San Donato
Servizio Sanitario Regionale Emilia-Romagna Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori"
IRCCS CROB Istituto di Ricovero e Cura a Carattere Scientifico
IEO Istituto Europeo di Oncologia
Fondazione IRCCS Policlinico San Matteo Sistema Socio Sanitario Regione Lombardia
istituto nazionale di gastroenterologia de Bellis - Castellana Grotte IRCCS
Gemelli Fondazione Policlinico Universitario Agostino Gemelli IRCCS Università Cattolica del Sacro Cuore
SYNLAB IRCCS SDN
IDI
HUMANITAS RESEARCH HOSPITAL
Maugeri
Fondazione Casa Sollievo della Sofferenza Opera di San Pio da Pietrelcina
Bambino Gesù Ospedale Pediatrico
Istituto di Candiolo IRCCS
Servizio Sanitario Regionale Emilia-Romagna
Istituto Superiore di Sanità
IOV Istituto Oncologico Veneto IRCCS
Istituto Nazionale Tumori
Servizio Sanitario Regionale Emilia-Romagna Istituto Ortopedico Rizzoli di Bologna Istituto di Ricovero e Cura a Carattere Scientifico

AVANIA

Stakeholders
Patient Societies!!

Stakeholders
Articles in press

healthcare-in-europe.com

World's first robot-assisted vascular surgery for aneurysm

London, UK - A Hansen Sensei robot has been used to perform vascular surgery on a 78-year-old patient for an aneurysm that would have been thought too high-risk for conventional surgery.*

During the operation a robotic catheter was manipulated by the surgeon at a console outside the operating theatre, using a steerable tip through the blood vessels. Viewing the blood vessels onscreen, a stent was accurately fitted in the aneu-

Final reflections

Do you now understand how a well though out market access & reimbursement strategy may positively influence market size and time to market?!

- **Market size**
  - Define target patient population
  - Clear definition of the comparative value proposition: Clinical stakeholder adoption
  - Indepth understanding of the patient access (treatment pathway / standard of care)
  - Indication of willingness to pay (Tariffs / competitor pricing)
  - Indication of the optimal business model (public / private sector)
- **Time to market**
  - Identification and anticipation of formal market access hurdles: coverage, coding and payment
  - Anticipate Evidence requirements (clinical and health economic)
  - Anticipate HTA requirement for coverage and adoption

So, if you take a structured approach and don't skip any step, you have already initiated a market access and reimbursement strategic plan!

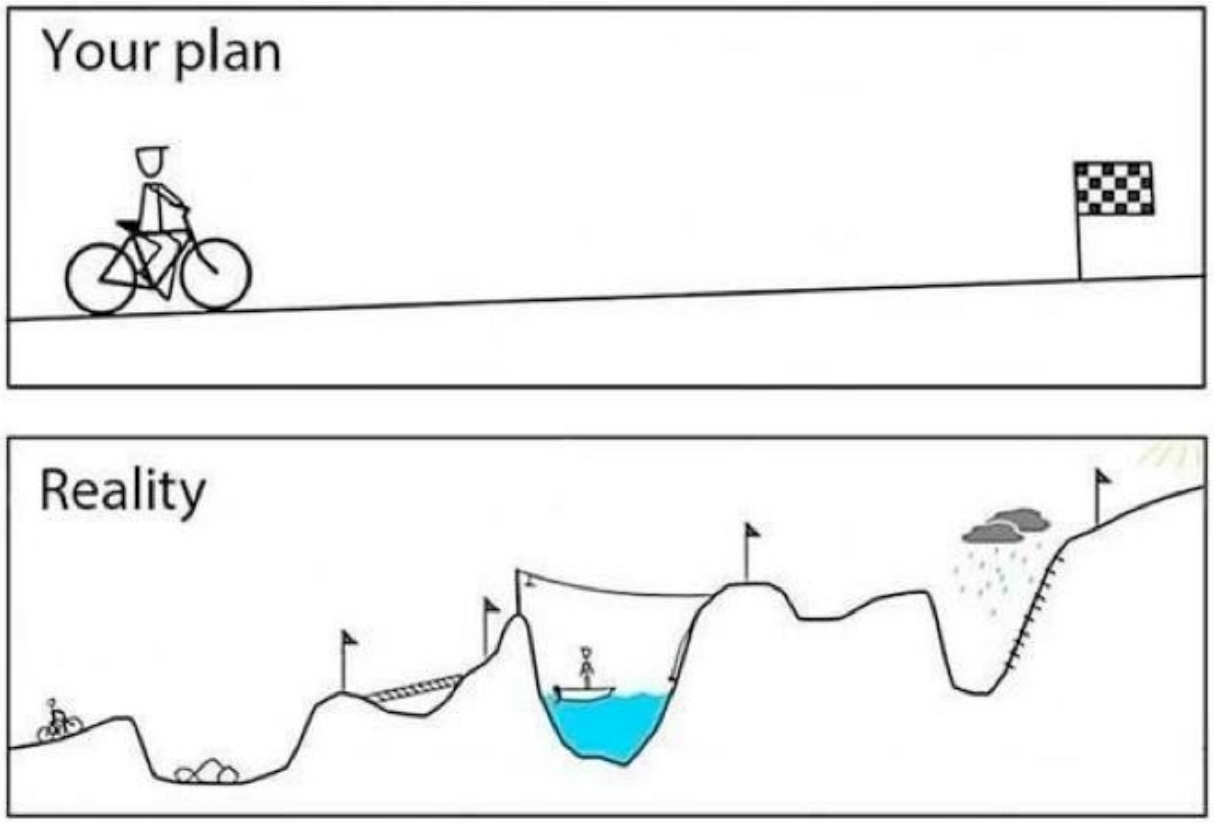
The answers to these questions for each market will provide you with the key elements of a market access strategy

	Market Access Strategy Development Questions
1	Is your technology covered in the market of interest in the public and / or private setting and at national and/or regional level?
2	How are care providers financed in your market of interest and how are they financed for the use of your technology?
3	What is the impact of coding and tariffs on market access in your target market?
4	What is the setting of care for your technology in the target market?
5	How is your technology coded in the target market?
6	Are existing tariffs sufficient to cover the cost of your technology? If not, are innovation pathways available?
7	What is the target indication and the initial utilisation of for your device?
8	Are there any guidelines on the treatment pathway of this indication and what are the recommendations?
9	Has a HTA been performed on your technology or a similar / competitor technology?
10	What is the role of patient societies on technology adoption, and are they relevant to your technology?

The answers to these questions for each market will provide you with the key elements of a market access strategy

	Market Access Strategy Development Questions
11	Where does your technology ”fit” in the patient treatment pathway for the target indication?
12	Who are the key clinical and economic stakeholders in this treatment pathway that contains your in the target market?
13	What is the current standard of care patient treatment pathway?
14	What is the unmet need?
15	How does your technology alter the SoC pathway and / or stakeholders involved?
16	Resource allocation is evaluated by each stakeholder with their own perspective of “Value”: How do stakeholders in your target market perceive the **comparative** value of your device (versus price and competitors)?
17	What scientific evidence will be required by clinical and economic stakeholders to back up the value proposition of your technology
18	What is the willingness to pay for your technology based on the comparative value proposition versus SoC and competitor technologies?
19	What is the preferred business model(s) in each setting of care and market?

Questions?



Meike Bomhof
Vice President Europe
Avania Market Access
meike.bomhof@avaniaclinical.com

Services

AVANIA

Global Capabilities Backed by Deep Expertise

900+ Discrete Projects

500+ Regulatory Submissions

400+ MD&D Trials

40+ Countries

25+ Breakthrough Designations

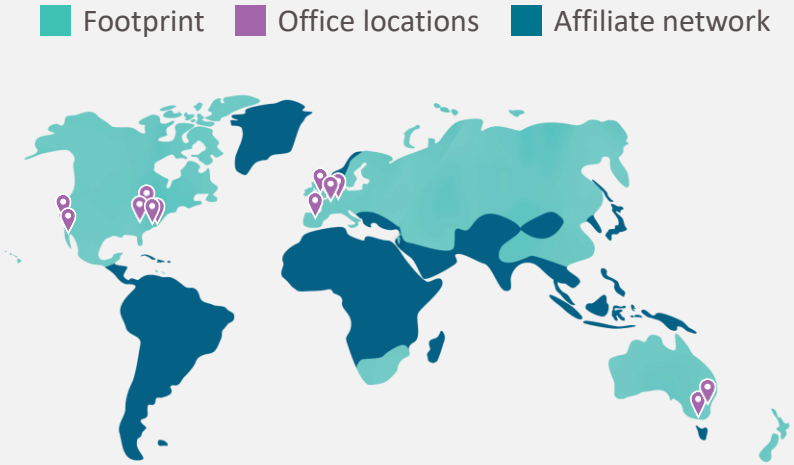
Industry Leading Certifications

ISO 9001 ISO 13485 ISO 27001

Fully Compliant With Industry Regulatory Frameworks

- **ISO 14155:2020** – Good Clinical Practice for Medical Devices
- **Code of Federal Regulations Title 21** – FDA Regulations of Medical Devices
- **GCDMP** – Good Clinical Data Management Practices
- **MDR** – Medical Device Regulation
- **IVDR** – In Vitro Diagnostic Regulation
- **GDPR** – General Data Protection Regulation

On a Global Scale



- **USA:** California (San Diego and San Jose), Massachusetts (Boston and Marlborough), Ohio (Cleveland)
- **EU:** Germany (Frankfurt), Netherlands (Bilthoven), Spain
- **AUS:** Melbourne, Sydney
- **UK:** Nottingham
- **CAN:** Toronto, ON

Qualified suppliers in following regions:
Eastern EU, Asia, Latin America

Product Types

- Device (Class I, II, III)
- In vitro diagnostics and point of care diagnostics
- SaMD/AI
- Imaging diagnostics
- Combination products
- MHealth (wearables & mobile devices)

AVANIA

Advancing Your Medical Technology From Innovation to Commercialization

	Discovery and Ideation	Invention and Prototyping	Pre-Clinical Testing	Clinical Trials	Regulatory Approval	Product Launch	Post-Market Support
Emerging Technology and Project Development Strategy	✓	✓	✓	✓	✓		✓
Data Analytics, Safety, and Compliance			✓	✓	✓		✓
Clinical Operations			✓	✓			✓
Market Access		✓		✓		✓	✓

AVANIA

Support from Concept to Commercialization

	Concept Development	Implementation	Clinical & Non-Clinical Testing	Market Clearance	Manufacturing & Operations	Market Access & Reimbursement
Capabilities	• Unified Regulatory, Clinical Evidence, Product Development and Market Access Strategy for Novel Products • Concept Development and Evaluation • Market Appraisals • Due Diligence & Scientific Evaluation • Human Factors & Industrial Design	• Systems Design • QMS Setup and Certification Management • Software Development (Embedded and Applications) to IEC 62304 • Electronic Development (EMC, 60601-1) • Mechanical & Industrial Design • Labeling, Operator's Manuals	• Clinical Trial Design & Strategy • Biostatistics • Software Validation • Biocompatibility & Toxicology • Sterilization & Shelf Life • EMC & Safety • Bench Testing & System Validation • Compliant Clinical Operations Support • Clinical Trial Design & Strategy • Animal Testing • Animal Study Design	• FDA Approvals (510k), PMAs, De-Novos • Technical File Development & CE Mark • Health Canada Licencing • Australia (TGA) • And other locations	• Ongoing QMS Support (Audits, Resolving Findings • Design for Manufacturing • Tooling Design	• Evidence Planning and Optimal Product Positioning • Field Support for Coverage, Coding and Payment • Economic Models and Health Economic Studies • Product Hotline Support
Typical Projects	• **Path to Market** • **FDA Pre-Sub** • **Breakthrough Designations** • **Orphan Product Designations** • **Special Access**	• **Turnkey Product Development** • **QMS Set-Up & Certification Support** • **Project Rescue** • **Design for Compliance**	• **Clinical Study Protocols & Reports** • **IDEs & ITAs** • **Verification and Validation** • **FCC/CSA/60601-1 Series Certifications**	• **Regulatory Submissions** • **Clinical Evaluations** • **Rescue of Failed Regulatory Submissions**	• **Device Master Record Generation** • **Contract Manufacturer Identification & Selection** • **Internal Audits** • **Audit Remediation**	• **Global Strategic Evidence Design** • **Coding Strategy** • **Health Economic Analysis to Support Product Value**

Integrated Solutions For Your Journey From Concept to Commercialization

Emerging Technology & Product Development Strategy

- Clinical and Regulatory Strategy Consulting
- Project Delivery
- Field Clinical Management

Clinical Operations

- Clinical Monitoring
- Late-Phase Project Delivery

Data Analytics, Safety, & Compliance

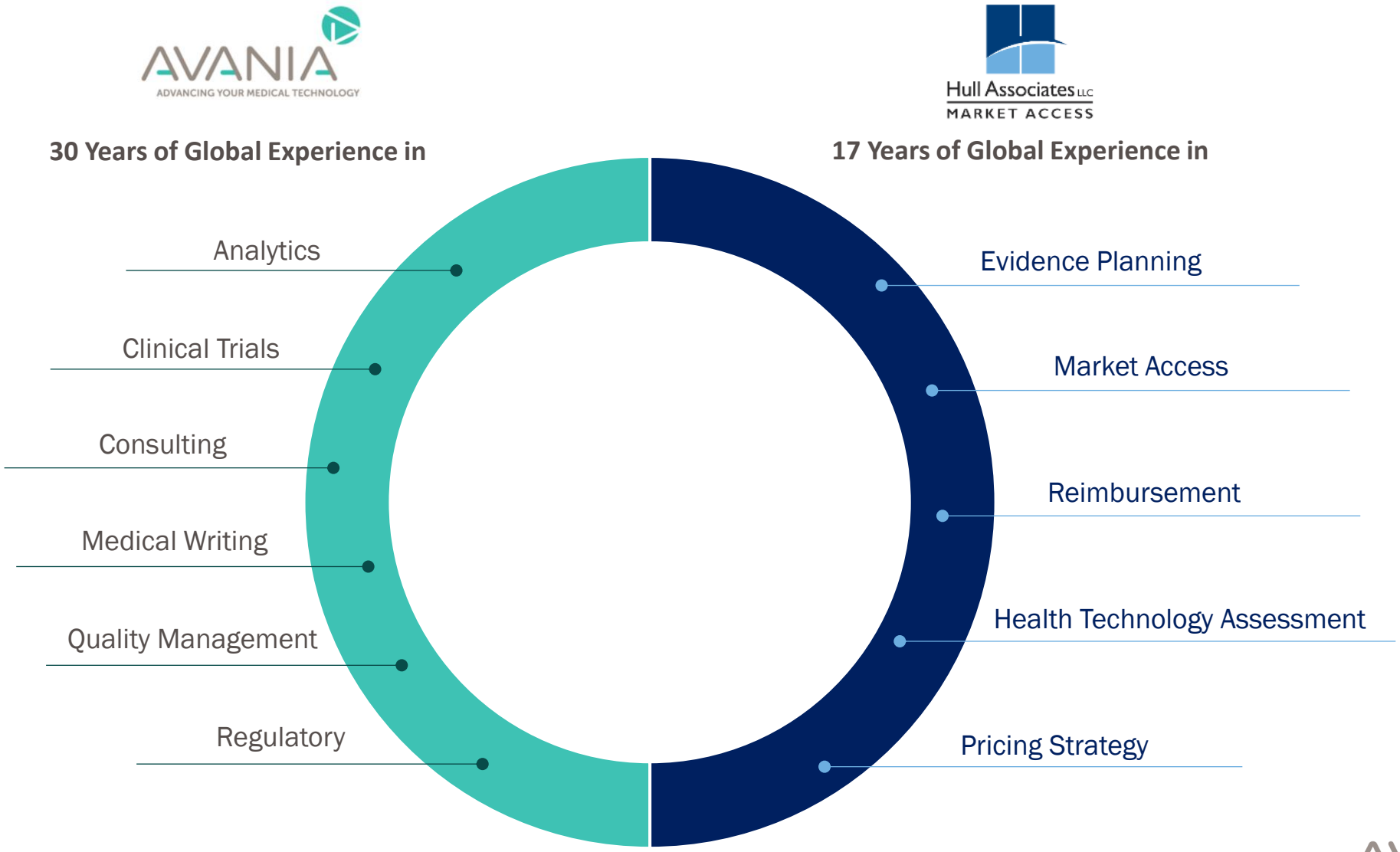
- Data Analytics
- Biostatistics
- Safety Management
- Regulatory and Medical Writing

Market Access

- Reimbursement Strategy & Market Access
- Patient Access & Support Center Services

AVANIA

The acquisition in 2023 of Hull Associates Market Access by Avania CRO integrates core expertise across the entire MedTech development and adoption pathway.



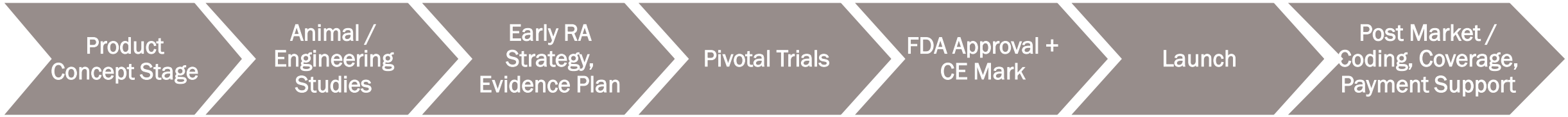
AVANIA

Market Access and Reimbursement services are applicable throughout the product lifecycle

Strategic consulting services span from early product development and evidence planning

They are most needed around the time of launch.

Product Lifecycle Stages



Market Access and Reimbursement Services by Product Stage

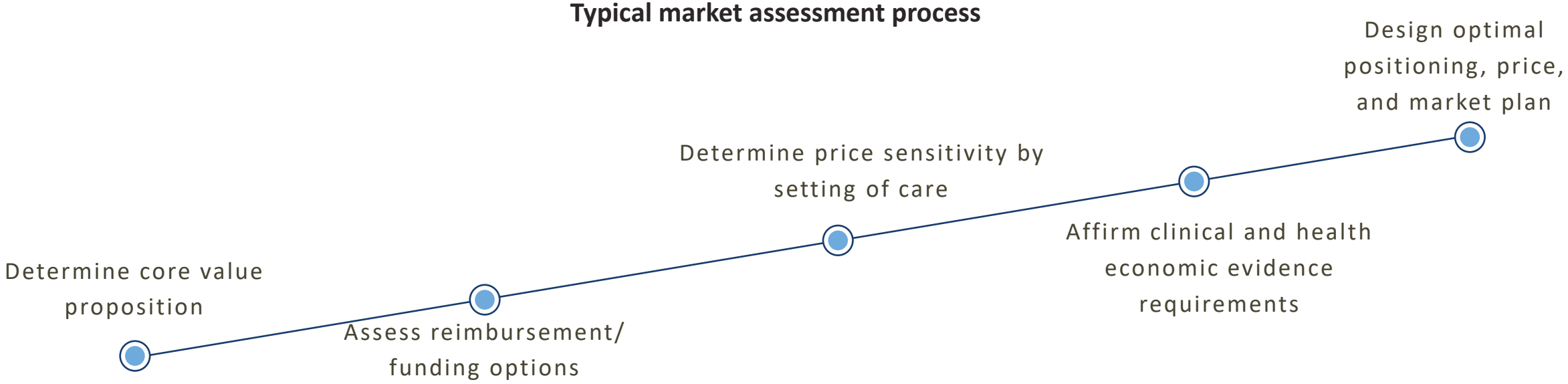
✓	x	✓	✓	x	✓	✓
• Early Market Access and reimbursement pathway analysis • Initial evidence plan		• Integrated clinical and resource utilization evidence design • Confirm critical path requirements	• Health economic evidence design & generation.		• Coordinate stakeholder support • Support RWE collection	• Apply for novel codes / coverage under evidence development • Design and support reimbursement • Dossiers for coverage / HTA reviews • Lifecycle MA&R support

A key function of the market access team is to advise clients on the evidence requirements to obtain market access and reimbursement and therefore the design of clinical and health economic evidence to achieve this goal, as well as CE / FDA marking and approval.

AVANIA

We offer a fully integrated assessment to obtain and improve reimbursement and market access

Typical market assessment process



Our field experts apply their knowledge of payment systems and health policy to a well-defined methodology for each product

- Assess and understand the product's core value in each local market context
- Understand the influences and opportunities for coverage and reimbursement
- Determine price sensitivity for adoption using the best adapted method for each market
- Affirm local evidence requirements to design an optimal clinical and health economic evidence strategy

AVANIA

Core Services – in all global markets

Strategic Advisory Services	• Reimbursement Assessment and Strategy • Evidence Planning • Product Positioning • Pricing Strategy, Value-Based Pricing™ Analysis
Health Economic Services	• Development of health economic models, prospective studies, and management of publication strategies in all international markets
Expert Focus Group Support	• Implementation of expert payer and key stakeholder focus groups in all major markets of the world
Reimbursement Execution and Advocacy	• Execution of targeted reimbursement strategies for specific products across multiple markets
Market Portfolio Management	• Ongoing support in international markets to manage product portfolio reimbursement and economics • Liaison support between distributors, local reps, and key stakeholders

AVANIA

Avania Market Access has local expertise & a worldwide reach allowing for strategic consulting, globally.

EXECUTIVE LEADERSHIP

Eric Lam, Phd

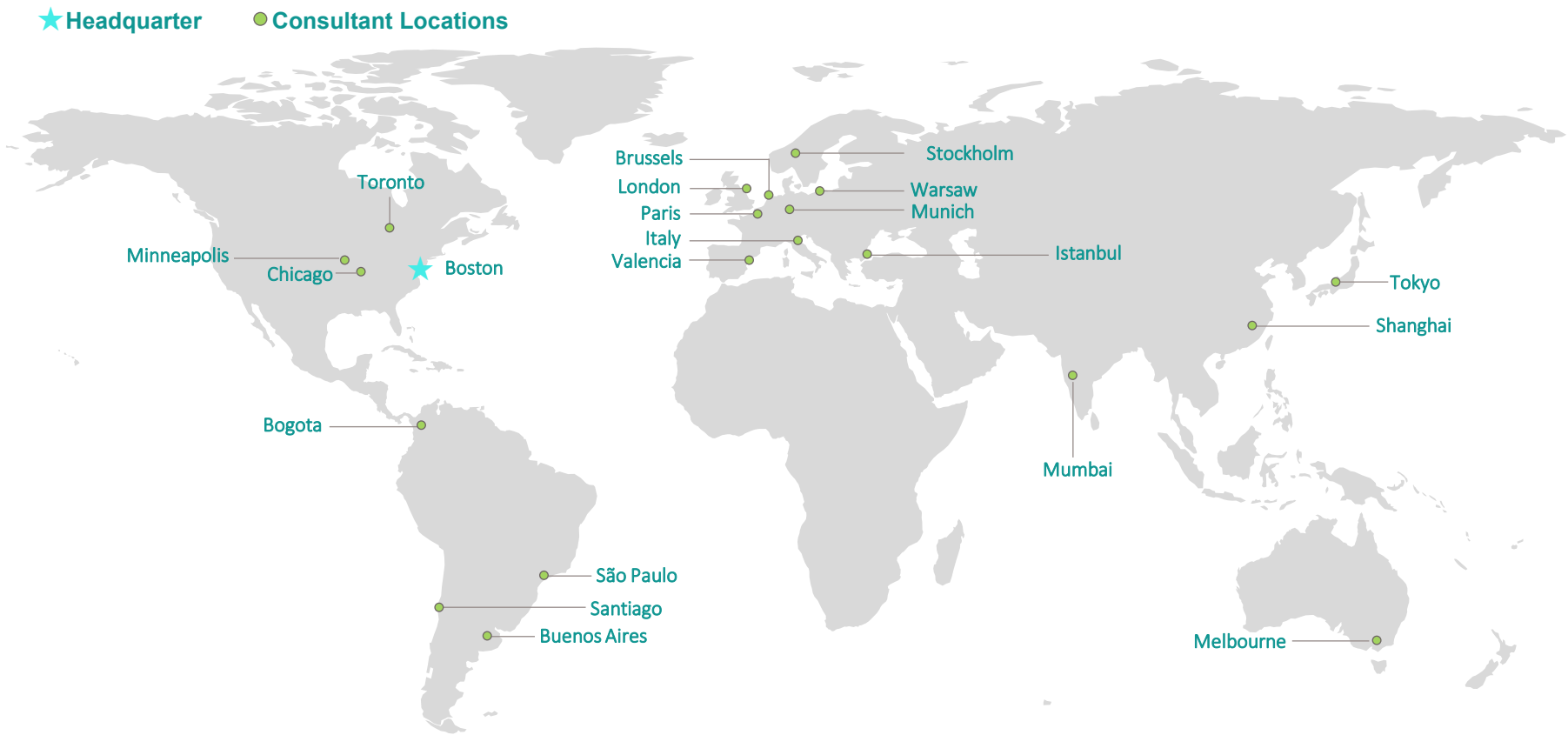
Sr. Vice President

Stephen Hull

Sr. Vice President

Meike Bomhof

Vice President, Europe



For the last 20 years we have served over 500 companies across multiple product areas

AVANIA

Thank you!