



# Market Access for Medical Technologies in Spain



Prepared for



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# Hospital Adoption Drives Market Access, While National Inclusion and HTA Strengthen Acceptance



## Reimbursement

**Mechanism to pay for technology or medical procedure**

- Market access is typically region- or hospital-based
- As there is no reimbursement system in Spain, and the hospitals operate within the global budget, the key factor for market access is the adoption by the actual users of the technology (healthcare providers)

## Acceptance by payers

**Independent acceptance by payers or national decision-makers**

- One factor that can significantly support acceptance by healthcare providers and locally is the explicit inclusion of the novel technology into the Common Package of Benefits at the national level

## Stand-alone HTA

**Stand-alone health technology assessment**

- Health technology assessment is developed at the local, regional, and national levels and supports decision-making about the introduction of novel technologies

# Spain's Global Budget System Is Governed by a Multi-stakeholder National-Regional Structure



## Policy-makers / Payers



### Ministry of Health

Determines high-level policy objectives, and quality requirements in health care, and has multiple other functions



### Health Ministries of Autonomous Communities

Responsible for contracting health care, financing, quality control, and priority setting for each of the 17 Autonomous Communities



### National Institute of Health Management (INGESA)

Responsible for the health care service of Ceuta & Melilla Autonomous Cities and for selected centralized procurement activities

## Policy-makers



Consejo Interterritorial  
SISTEMA NACIONAL DE SALUD

### Interterritorial Council for the NHS (CISNS)

Determines coverage of health care services within the Common Package of Benefits, designates Benchmark centers, departments, and units of the National Health System (CSURs)

## Decision influencers



### Commission of Benefits, Insurance, and Financing

Makes proposals on the update of the Common Package of Benefits of the NHS. Works under the Interterritorial Council for the NHS



RED ESPAÑOLA DE AGENCIAS DE EVALUACIÓN  
de Tecnologías e Intervenciones de Salud (RedETS)

### Spanish Network of HTA Agencies (RedETS)

Network of health technology assessment agencies. Formed by seven regional HTA units and the national one. Performs health technology assessments and gives technical support to the NHS. Coordinates HTA activities required to inform the inclusion of new services into the Common Package of Benefits of the NHS. Also coordinates the development of the national clinical guidelines



# Healthcare Payment in Spain Differs by Population Group, Led by Global Budgets

## General public

- Covered by the NHS (actual payers are the Autonomous Communities)
- Healthcare is funded using a global budget principle
- Autonomous Communities maintain price lists, which are used for reimbursement of services provided to the uninsured (typically foreigners) and some other small groups. However, these tariffs are not applicable to the general population

## Specific groups of citizens

- Includes public servants, military, and judicial branch workers
- These groups of citizens are covered by specific Mutual Funds (MUFACE – for civil servants, MUGEJU – for justice workers, and ISFAS – for armed forces)
- Mutual Funds maintain price lists, which are used for reimbursement of services provided to their covered population outside Spain (when they travel)

## Foreigners and citizens with private insurance

- Individual insurance companies have confidential agreements with healthcare providers
- Payment mechanisms and tariffs are not publicly disclosed

Care provided can be reimbursed using different payment models depending on the different citizen categories. The majority of care is the care provided to the general public, which is reimbursed via the global budget payment mechanism



## Example: Hospital Budgets Are Driven by Activity Metrics Defined at the Regional Level

Type of care		Catalonia	Andalusia	Basque Country	Valencia
Hospital stay	Any type	1.00	-	1.00	1.00
	Medical	-	1.00	-	-
	Surgical	-	1.00	-	-
	Obstetrics	-	1.20	-	-
	Pediatrics	-	1.30	-	-
	Neonatology	-	1.30	-	-
	Intensive care unit	-	5.80	-	-
Surgery with hospitalization		-	2.00	-	-
Ambulatory surgery		0.50	0.25	0.75	1.00
Outpatient consultation	First	0.50	0.25	0.40	0.40
	Follow-up	0.25	0.15	0.20	0.20
Emergencies		0.40	0.30	0.40	0.50
Dialysis		-	-	1.28	-
Rehabilitation (session)		-	-	0.10	-
Day hospital		-	10.00	-	-

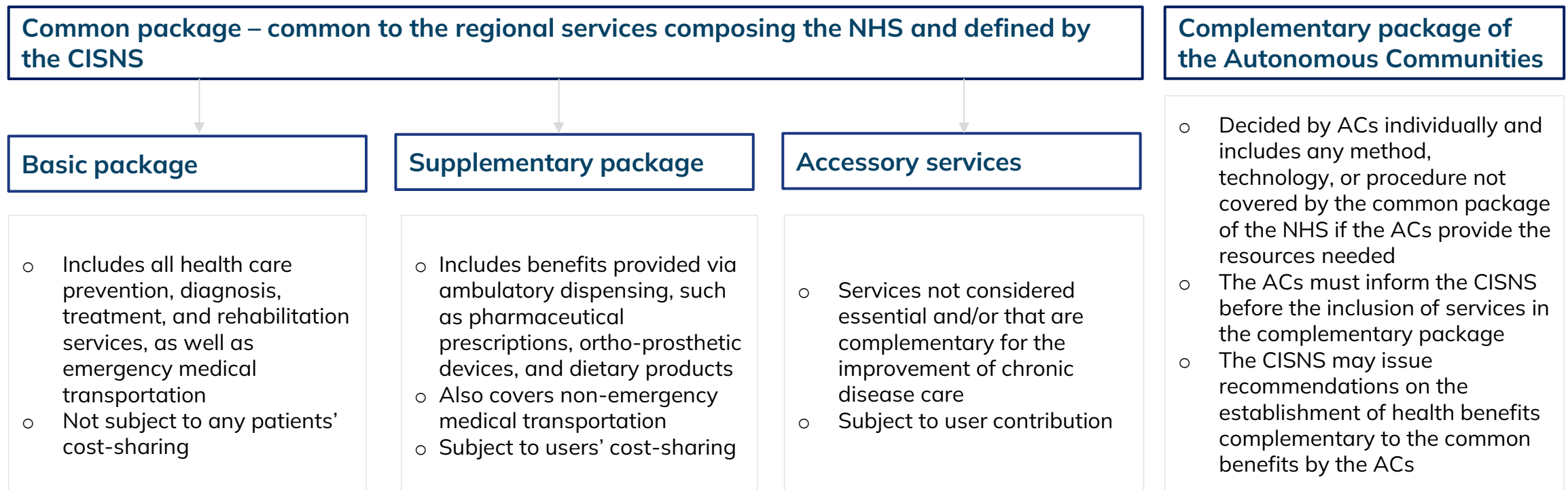
Hospital budget is determined by a number of factors, but the most important are the historical budget and the hospital's activity measured in the form of production units



# Market Access in Spain Follows a Nationally Defined Benefits Framework with Regional Flexibility



- There is no reimbursement, but only an acceptance by payers' framework in Spain. The package of benefits is defined by the Interterritorial Council for the National Health System ([CISNS](#)), composed of the Health Ministers of the Autonomous Communities (ACs), and the Health Minister of Spain
- The [Royal Decree 1030/2006](#) establishes the Common Package of Benefits provided within the NHS and the procedures for its update. According to the [Royal Decree 16/2012](#) regarding urgent measures to guarantee the sustainability of the NHS and improve the quality and safety of its services, the package of benefits is categorized into two types of services (common package and complementary package of the Autonomous Communities):





# Spain's Common Package of Benefits Is Centrally Defined and Updated on an Ongoing Basis

## Common Package of Benefits of the NHS: Definition

- It is the set of techniques, technologies, or procedures, understood as each of the methods, activities, and resources based on scientific knowledge and experimentation, through which health benefits are made effective
- It is common for all regions of Spain, and then each Autonomous Community has its complementary package
- The services it contains are considered basic and common, understood as those necessary to provide adequate, comprehensive, and continuous health care for all users of the NHS. It must guarantee comprehensive care and continuity of the assistance provided to users, regardless of the level of care to which they are attended at all times

## Continuous updates

- The decision to include new technologies in the Common Package of Benefits of the NHS is made by the Interterritorial Council for the NHS (CISNS) upon the proposals submitted by the Commission of Benefits, Insurance, and Financing, and the (mandatory) technical advice of the Spanish Network of HTA Agencies (RedETS)
- The updates usually start with requests made by the different Autonomous Communities (ACs), but they can also be made by the Ministry of Health or at the initiative of third parties (although not so common)
- The Common Package of Benefits of the NHS is subject to ongoing review. In recent years, it has been typically amended one to several times annually

## Regional implementation

- ACs have the right to make regional coverage decisions to guarantee the provision of certain medical technologies to their citizens
- Most ACs only adopt the national Common Package of Benefits, whereas some ACs implement their own regional package of benefits, and others publish coverage decisions for individual medical technologies (e.g., Aragon, Galicia)



# Spain's Common Package of Benefits Is Category-based, with Flexibility at Provider and Regional Level



## Categories of care guaranteed by the Common Package of Benefits

Public health benefits

Primary care

Prescription (outpatient) medicines

**Specialized services (including specialized care in consultations, hospital admission, day case, diagnostic and therapeutic procedures, home hospital, etc.)**

**Ortho-prosthetic benefits (implants, some medical aids such as wheelchairs)**

Emergency care

Dietary products

Medical transportation

- The Common Package of Benefits does not provide an exhaustive (positive) list of covered services. Instead, it defines the covered services vaguely. Healthcare providers have the right to choose the procedures and technologies which they will use to deliver healthcare
- Regarding ortho-prosthetic benefits, the categories of covered devices, but not brands, are listed
- Each Autonomous Community may have its complementary package in addition to the Common Package of Benefits

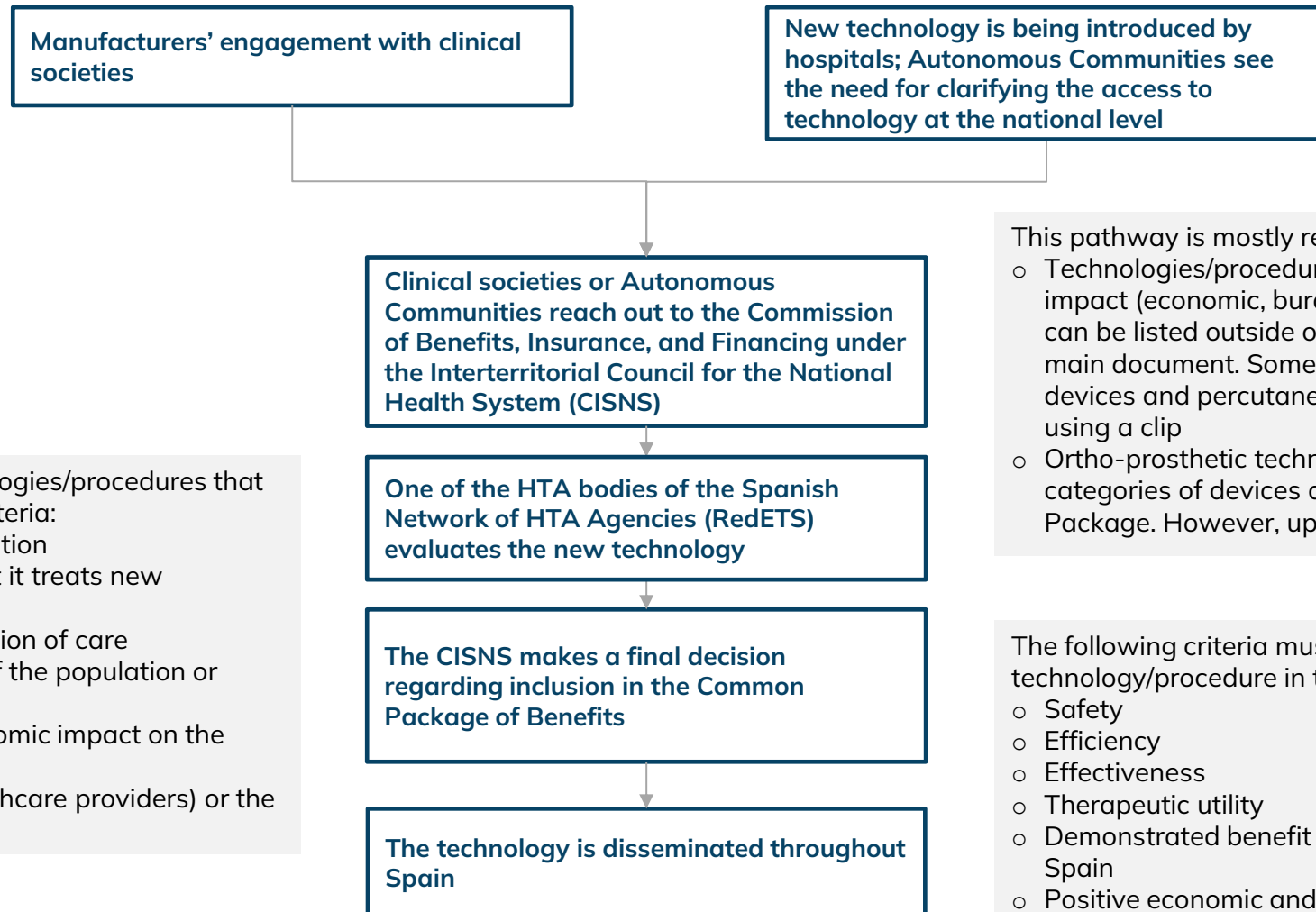
**Surgical implants**

External prostheses, wheelchairs, orthoses, special orthoprotheses

Groups and sub-groups of devices in this category do not have nationally defined tariffs. The healthcare providers are obliged to purchase the implants that will be used during surgical procedures



# Regional or Clinical Initiatives Drive HTA Assessment and CISNS Decisions on Updates of the Common Package of Benefits



HTA is required for technologies/procedures that meet at least one of the criteria:

- It is a substantial innovation
- It is already covered, but it treats new indications
- It modifies the organization of care
- It affects large groups of the population or groups at risk
- It has a significant economic impact on the NHS
- A risk to the users (healthcare providers) or the environment is expected

This pathway is mostly relevant for:

- Technologies/procedures that will have a significant impact (economic, burden of disease) nationwide. These can be listed outside of the Common Package of Benefits main document. Some of the examples are CGM/FGM devices and percutaneous mitral valve repair systems using a clip
- Ortho-prosthetic technologies (e.g., implants), as these categories of devices are explicitly listed in the Common Package. However, updates occur rarely

The following criteria must be met to introduce a new technology/procedure in the Common Package of Benefits:

- Safety
- Efficiency
- Effectiveness
- Therapeutic utility
- Demonstrated benefit vs comparator already used in Spain
- Positive economic and social impact

# HTA Determine Inclusion, Exclusion, or Conditional Use in Spain's Common Package of Benefits



## Evaluation methodology

The following parameters are assessed to decide on the inclusion of new methods, technologies, or procedures (MTPs) in the Common Package of Benefits:

- Safety
- Efficiency
- Effectiveness
- Therapeutic utility of the MTPs
- Advantages and alternative care
- The care of less protected groups and social needs, and their economic and social impact

## Possible outcomes

The MTP is safe, efficient, and effective

**Inclusion in the Common Package of Benefits**

Doubts about the safety, effectiveness, or efficiency

**Supervised Use** - a form of coverage with evidence development *before* the inclusion in the Common Package of Benefits

Doubts about the use in clinical practice

**Monitoring Study** - a form of coverage with evidence development *after* the inclusion in the Common Package of Benefits

The MTP is neither safe, efficient, nor effective

**Exclusion / non-inclusion** in the Common Package of Benefits

The proposal for inclusion of new methods/technologies/procedures (MTPs) in the Common Package of Benefits of the NHS will be accompanied by a technical report prepared by the HTA bodies that includes the results of the assessment, the bioethical and social consequences, and an economic report that contains the assessment of the impact of the new MTP

# Example: CISNS Approval Decision for Real-Time Continuous Glucose Monitoring (rt-CGM)

## Regulatory decision

- On July 22, 2021, the Resolution of the General Directorate of the Common Package of Benefits of the National Health and Pharmacy System was published

## Eligibility criteria

- The rt-CGM may be indicated by endocrinologists in the NHS as an alternative to blood glucose test strips for adult patients (18 years of age or older) with type 1 diabetes mellitus and:
  - risk of severe hypoglycemia (at least one episode of severe hypoglycemia during the previous year or due to inadvertent hypoglycemia),
  - who undergo intensive insulin therapy (multiple daily doses or an insulin pump),
  - who require at least six fingerpricks a day for self-monitoring of blood glucose,
  - and who show adequate motivation to maintain good adherence to the device
- Criteria for withdrawal of funding for the device were defined as well

## Implementation deadline

- The deadline for Autonomous Communities to incorporate the financing of rt-CGM in their regional frameworks for those patients who meet all the mentioned requirements was June 30, 2022

Interterritorial Council for the National Health System (CISNS) approval decisions can define national access conditions for specific technologies. One of the examples is real-time continuous interstitial glucose monitoring (rt-CGM) systems



# HTA Informs Both National Benefit Inclusion and Regional Adoption Decisions in Spain

## HTA within the Spanish Network of HTA Agencies (RedETS) framework

- The CISNS formally established the Spanish Network of HTA Agencies (RedETS) with the mandate of evaluating technologies to support decisions on the inclusion, exclusion, and modification of the Common Package of Benefits
- Under the applicable regulatory framework, HTA reports produced by RedETS are mandatory for decisions on the inclusion, exclusion, or modification of benefits
- The operation of the RedETS is regulated by Order SSI/1833/2013, which creates and regulates the Council of the RedETS
- The network coordinates the work of seven regional entities (in Andalusia, Aragon, the Basque Country, the Canary Islands, Catalonia, Galicia, and Madrid) and the national Agency, the Health Institute Carlos III, and seeks to prioritize studies, coordinate projects, and standardize methodologies
- The work of the network is based on the Annual Plan elaborated by the technical secretary of the RedETS and approved by the Council of the RedETS and the CISNS. For the development of the Annual Plan for the RedETS, the 1<sup>st</sup> step involves the identification and prioritization of the proposed topics for evaluation. The topic suggestions are made by the Autonomous Communities

## Regional HTA outside RedETS

- In addition, the HTA bodies of individual Autonomous Communities may develop HTA reports to inform decision-making in these ACs only
- As an example, the Health Technology Assessment Office of the Principality of Asturias (OETSPA) is not a part of the RedETS, and the HTA reports developed by this body are used to inform recommendations on the introduction, modification, or exclusion of products and technologies in the clinical practice of the centers of the Health Service of the Principality of Asturias (Sespa) only

- Health technology assessment is implemented at the national, regional, and hospital levels in Spain
- The objective of the HTA framework is twofold: to inform the inclusion of new services into a Common Package of Benefits of the NHS, and to inform regional or hospital decision-making about the acceptance of new methods
- The Ministry of Health is working on a new regulatory framework for the evaluation of health technologies, and the draft Royal Decree on this subject was published in 2024. This draft decree proposes to regulate HTA activities, including evaluations of medical procedures, devices, and diagnostics, to support evidence-based funding decisions in the NHS

# Spain Applies Limited Innovative Payment Schemes Linked to Evidence Generation

Spain has two innovative payment schemes in connection with the development of the Common Package of Benefits  
Both schemes can be classified as **coverage with evidence development (CED)**

## Supervised Use

- The CED scheme can apply **before** the inclusion in the Common Package of Benefits
- No new entrants since 2010

## Monitoring Study

- The CED scheme can apply **after** the inclusion in the Common Package of Benefits
- Actively used

## Eligibility criteria

- The scope of the programs includes any types of methods, technologies, and procedures (MTPs) suitable for inclusion in the Common Package of Benefits of the NHS (including hospital settings, outpatient specialist settings, and home-care settings)
- General criteria for the MTP to be considered relevant for inclusion within these two schemes are:
  - Representing a substantially novel contribution to prevention, diagnosis, treatment, rehabilitation, improvement of life expectancy, or elimination of pain and suffering
  - Having new indications for existing equipment or products
  - Requiring new specific equipment for their application
  - Significantly modifying the forms or organizational systems of patient care
  - Affecting broad sectors of the population or risk groups
  - Assuming a significant economic impact on the NHS
  - Posing a risk to users or health professionals, or the environment

# Examples of Technologies or Procedures Considered by the Monitoring Study Scheme

Method	Evaluation agency	Required sample size	No. of referral centres
Biodegradable oesophageal stent for benign pathology	ISCIII, national	83	17
Endobronchial valve for patients with persistent air leakage	SESCS, Canary Islands	40	9
Percutaneous mitral valve repair system by clip	OSTEBA, Basque Country	140	24
Closure device (Occluder) of the left atrial appendage	ISCIII, national	150	27
Atrial assist device (LVAD) in the indication of permanent destination therapy	ACIS / Avalia-t, Galicia	30	No data
Glucose Monitoring System using sensors (Flash type) for type 1 diabetes mellitus in childhood and adolescence	SESCS, Canary Islands	343	27
HIFU in the treatment of movement disorders	SESCS / AQuAS, Canary Islands / Catalonia	No data	No data

Note. Required sample size, and no. of referral centers are provided according to: Serrano-Aguilar P et al. (2021). Post-launch evidence-generation studies for medical devices in Spain: the RedETS approach to integrate real-world evidence into decision-making. *International Journal of Technology Assessment in Health Care* 37, e63, 1–8. <https://doi.org/10.1017/S0266462321000295>

- Since the inception of the scheme, several MTPs have been included in the scheme. Several monitoring studies of MTPs have been completed, while others remain ongoing
- Historically, the time from approval of the Monitoring Study to report publication has ranged from four to nine years
- According to the RedETS planning documents, new MTPs may be approved for inclusion in the scheme on a periodic basis (e.g., high-intensity focused ultrasound [HIFU] for movement disorders)
- Some examples of the Monitoring Studies are provided in the table



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