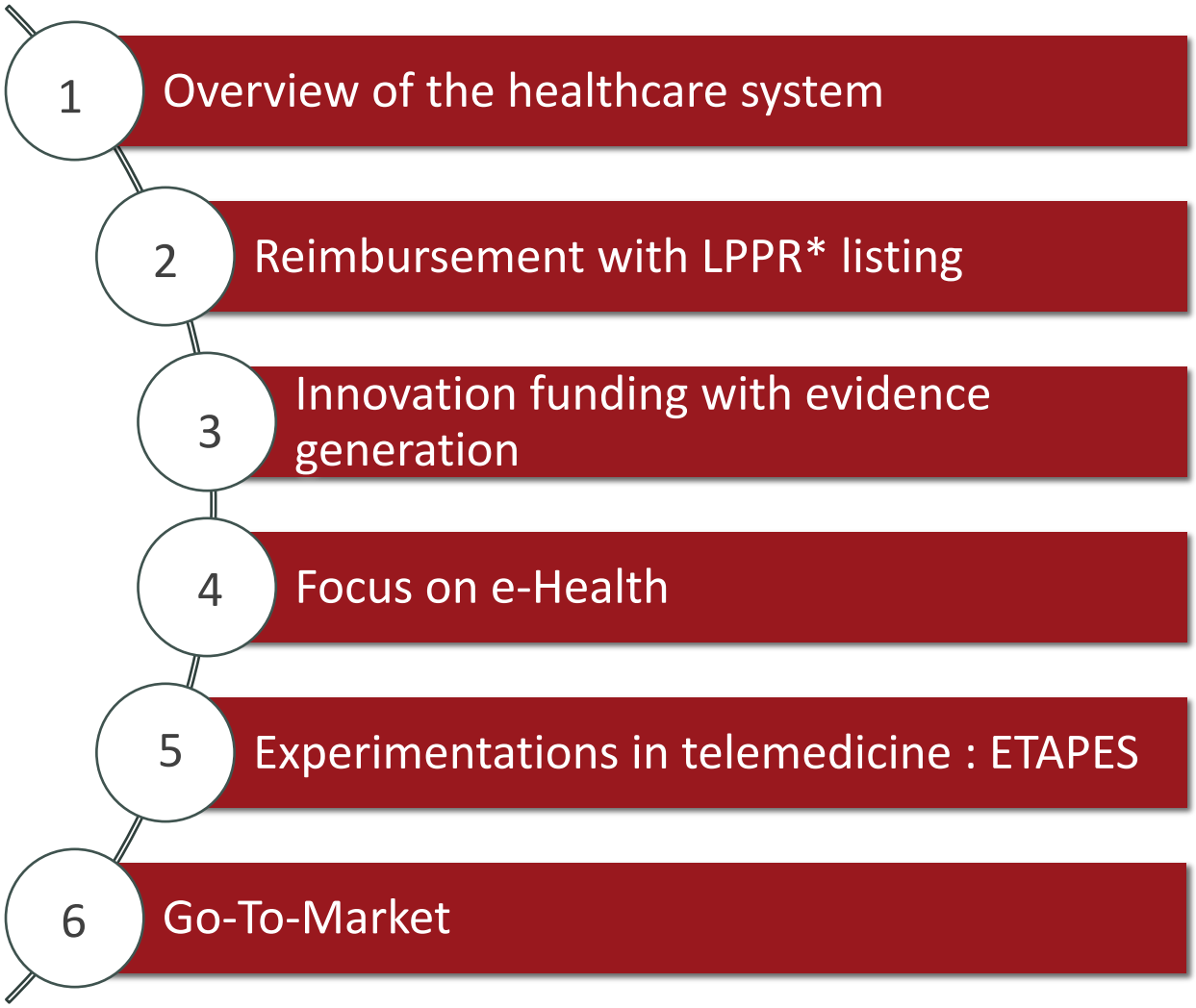
MARKET-ACCESS PATHWAYS

FRANCE

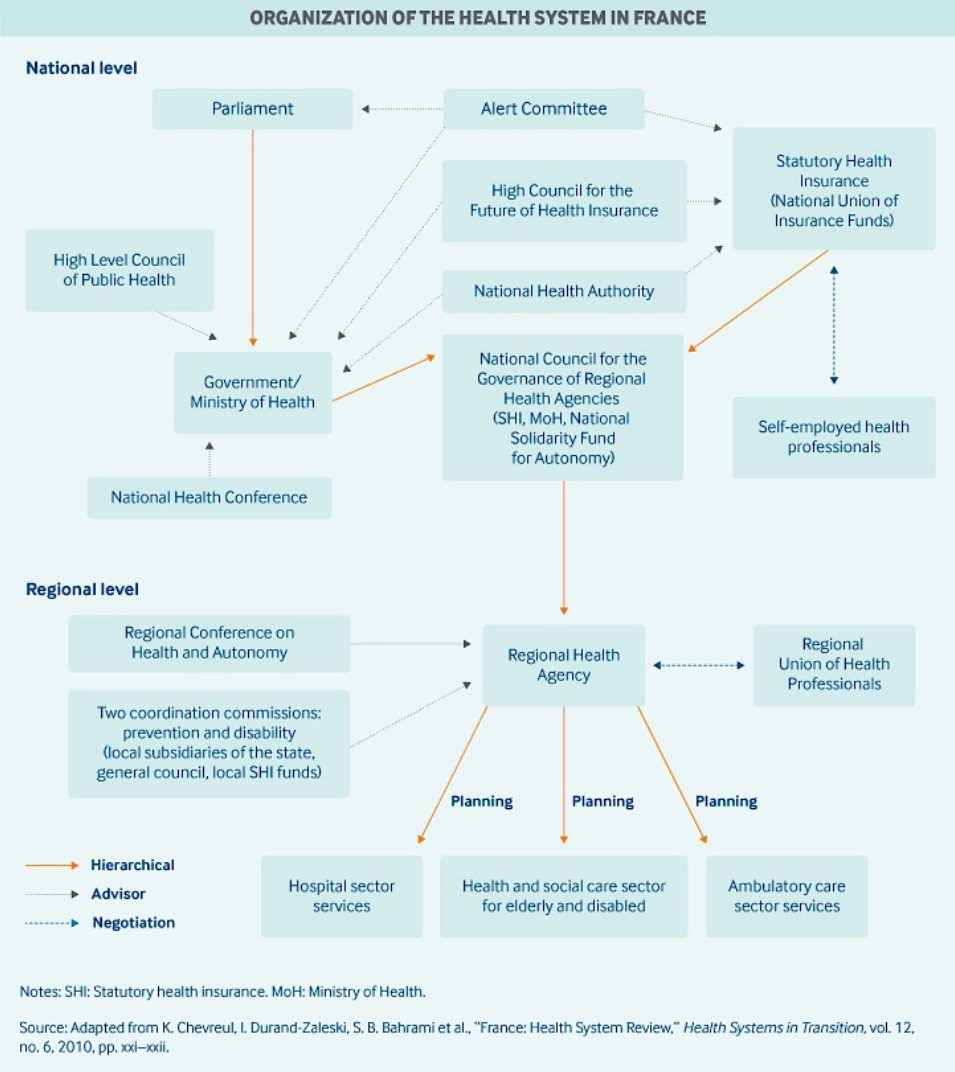
Summary



*LPPR: Liste des produits et prestations remboursables *(List of reimbursable products and services)*

1. Overview

Overview
The French Healthcare System:
Insurance-Based and Centralized Decision Making System



The Ministry of Health and Solidarity is the supervisor of the national funds. In France there are two major national funds and several smaller ones. The General fund (covering 90 % of the population) includes:

- regional funds (within the ARSs)
- local funds (CPAMs)

HAS - Is the independent national HTA organization

CNEDiMTS - Evaluates medical devices, diagnostics and therapeutic procedures:

- **SEAP Committee** - Evaluates clinical benefits of diagnostics and therapeutic procedures
- **SED Committee** - Evaluates clinical benefits of medical devices

CEPS - Is the French pricing body for medical products

ATIH - The technical hospitalization information agency maintaining the DRG system

UNOCAM is the union of voluntary health insurers

Key regional bodies are regional agencies of health **(ARSs)**, and regional unions of healthcare professionals (self-employed professionals) (**URPSs**).

Overview
Financing of the french health system

2018

78,1%
Universal Public Health Insurance

+

13,4%
Voluntary complementary private insurance

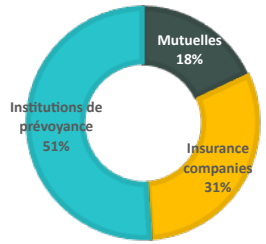
+

1,5%
Government

+

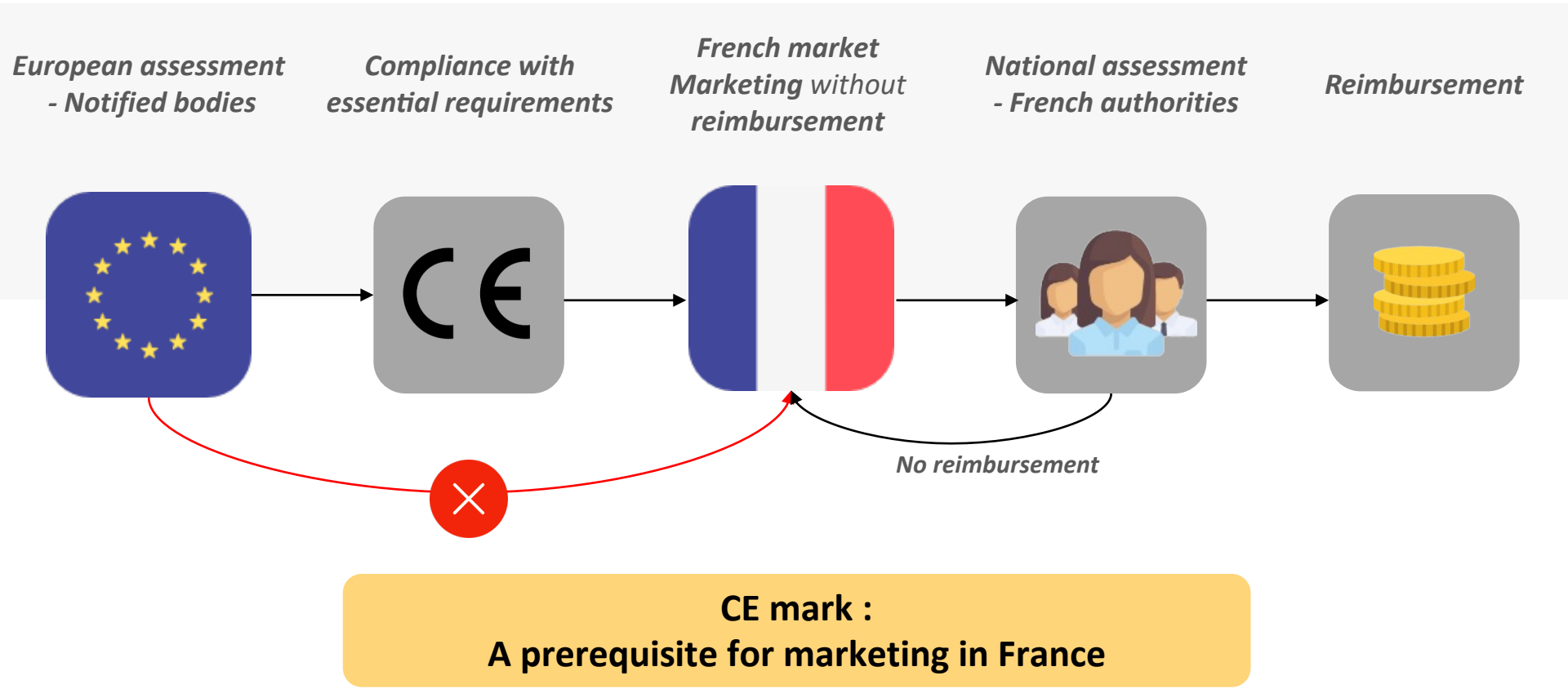
7 %
Low out-of-pocket (againt 16% in the UE)

- Mutuelles
- Insurance companies
- Institutions de prévoyances



Source : DREES

Overview
Access to the French market



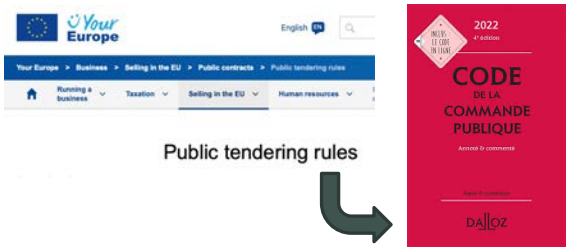
CE mark :
A prerequisite for marketing in France

Overview

Public hospitals vs private clinics

3 keys of entrance : Intra-DRG or Reimbursed price on LPPR or Dedicated medical code for procedure *

Public hospitals
- University hospitals
- Regional hospitals
- Local hospitals
- Oncology centers



Group purchasing organizations

UGAP, UniHA, resah Réseau des Acheteurs Hospitaliers, unicancer

- Group of private clinics
- Independant clinics

Bids & tenders specfic to each group / clinic

Ramsay Santé, VIVALTO SANTÉ, Almaviva santé, ELSAN Notre Santé autrement

Play by the book :

1. Do NOT expect to penetrate sustainably the market without one of the 3 keys of entrance*
2. Private insurances are NOT key stakeholders to get successful for bids and tenders
3. Patients do NOT have the choice to select / to pay for the device / the solution paid by Social Security
4. Direct to patient communication is NOT allowed to promote an healthcare good paid by Social Security

* There is an alternative case by case possibility with some local innovation funding

Overview
Key factors for market access

Clinical benefit → **Economical benefit**

France Switzerland Germany Japan

Evidence-based decisions clinical data

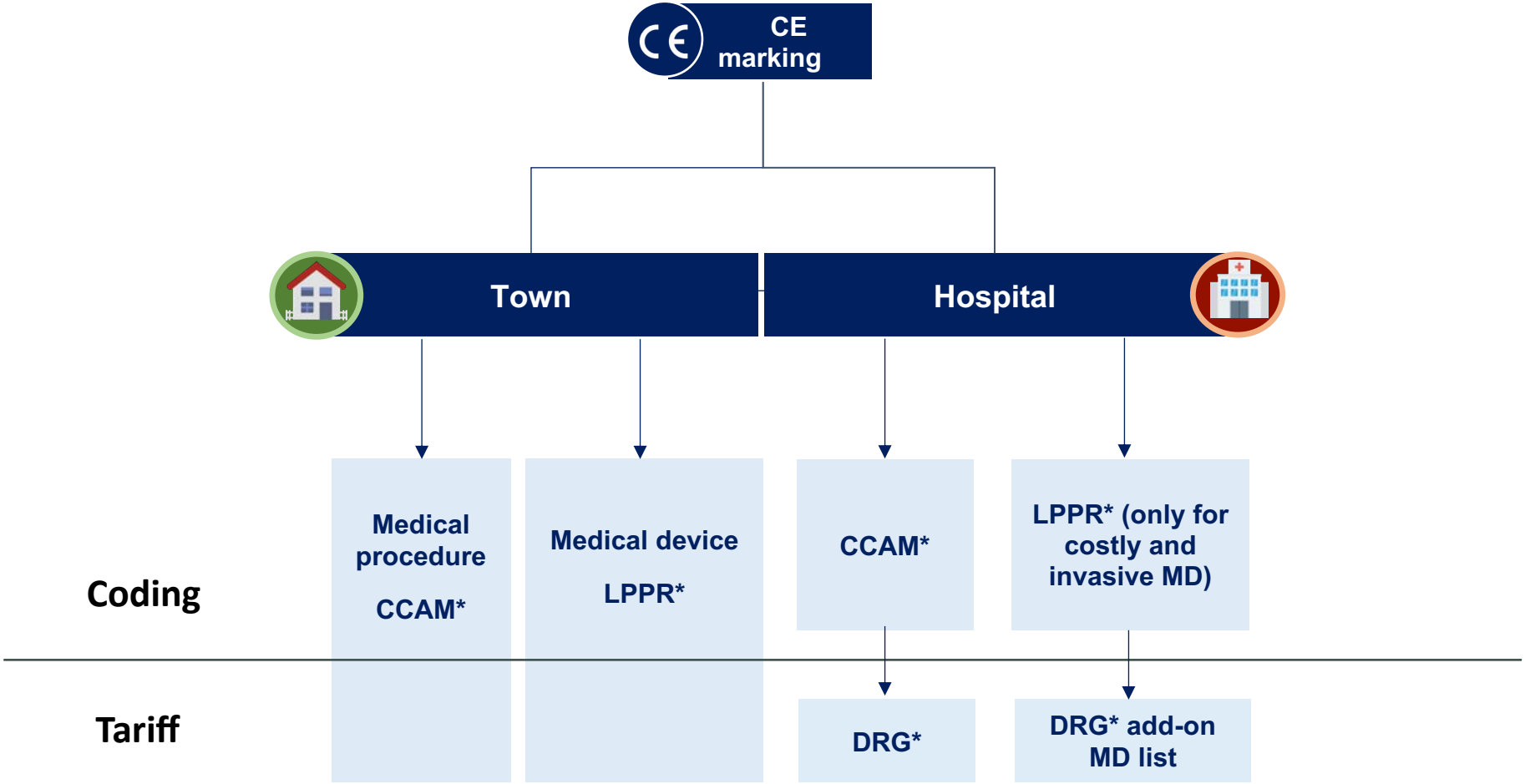
UK Canada Netherlands Australia Sweden

Decisions based on cost-effectiveness data

Brazil Spain Italy China

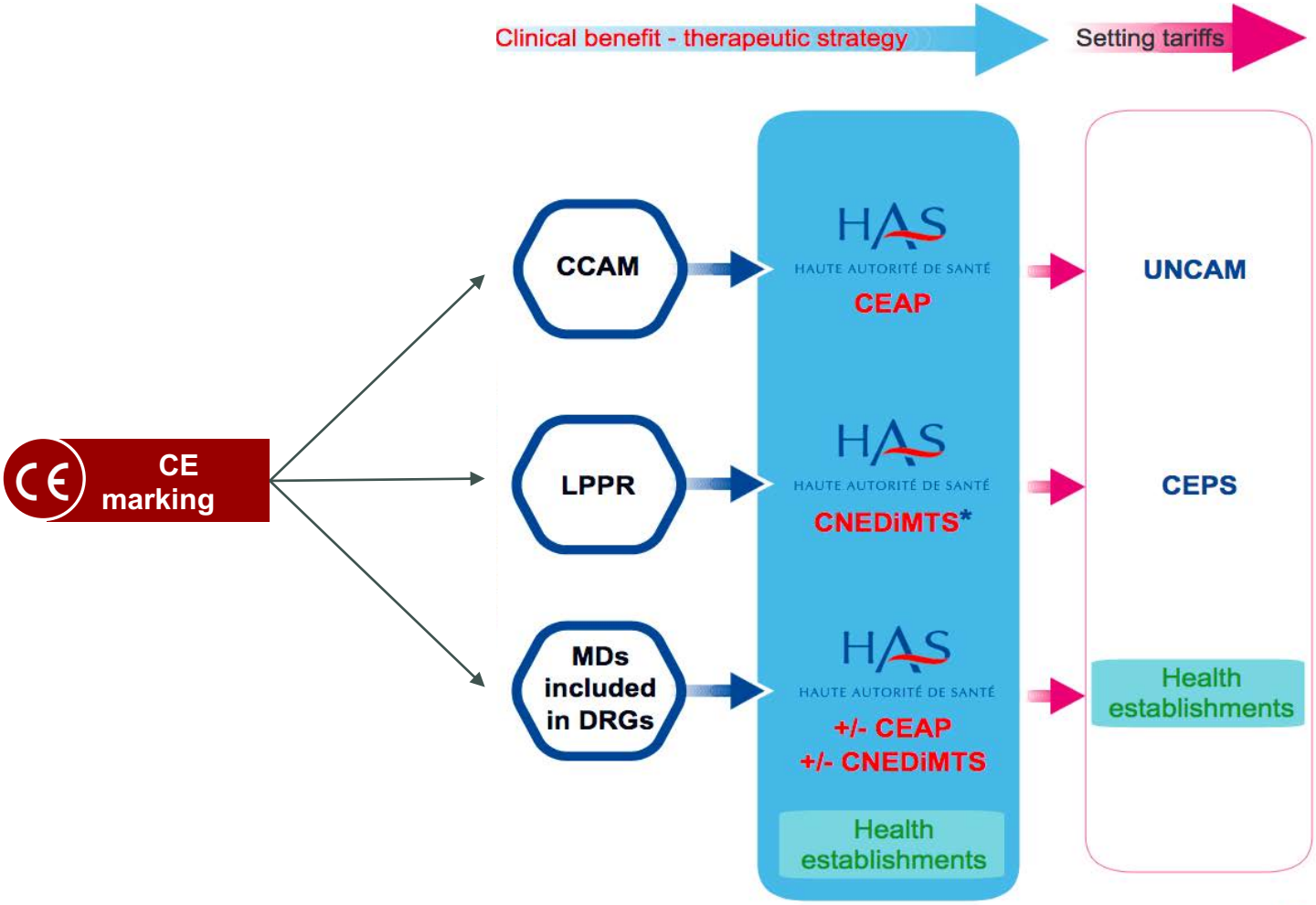
Decisions based on budgetary impact data

Overview
Funding in the outpatient sector and in the hospital



*CCAM: Classification commune des actes médicaux *(Common Classification of Medical Procedures);* DRG: Groupe homogène de malades *(Diagnosis related group);* LPPR: Liste des produits et prestations remboursables *(List of reimbursable products and services)*

Overview
Medical device market access: How to process?



** CCAM: Common Classification of Medical Procedures; CEPS: Economic Committee for Health Products; CNEDMITS: Authority assessing medical devices; DRG: Diagnosis Related Group; LPPR: List of Reimbursable Products and Services; UNCAM: National Union of Health Insurance Funds*

Overview
General considerations on access to the hospital market

Activity based funding (funding through DRG*)

Hospital stay
Lump sum payment for in- and out-patient care

DRG

Specific budgets
For expensive drugs and medical devices that induce a cost heterogeneity within a GHS

For expensive invasive MDs
Reimbursed at 100%
On top of DRG tariffs

Other funding

MIGAC* envelopes
Mainly for CHR/CHU and specialized nonprofit centers

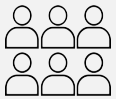
Innovation
Research
Education

Administrative information

Age | Length of stay | Sex

Clinical information

Diagnosis (ICD*) | **Procedure (CCAM*)**



DRG* (Diagnosis Related Group)
GHM ("Groupe Homogène de Malades")

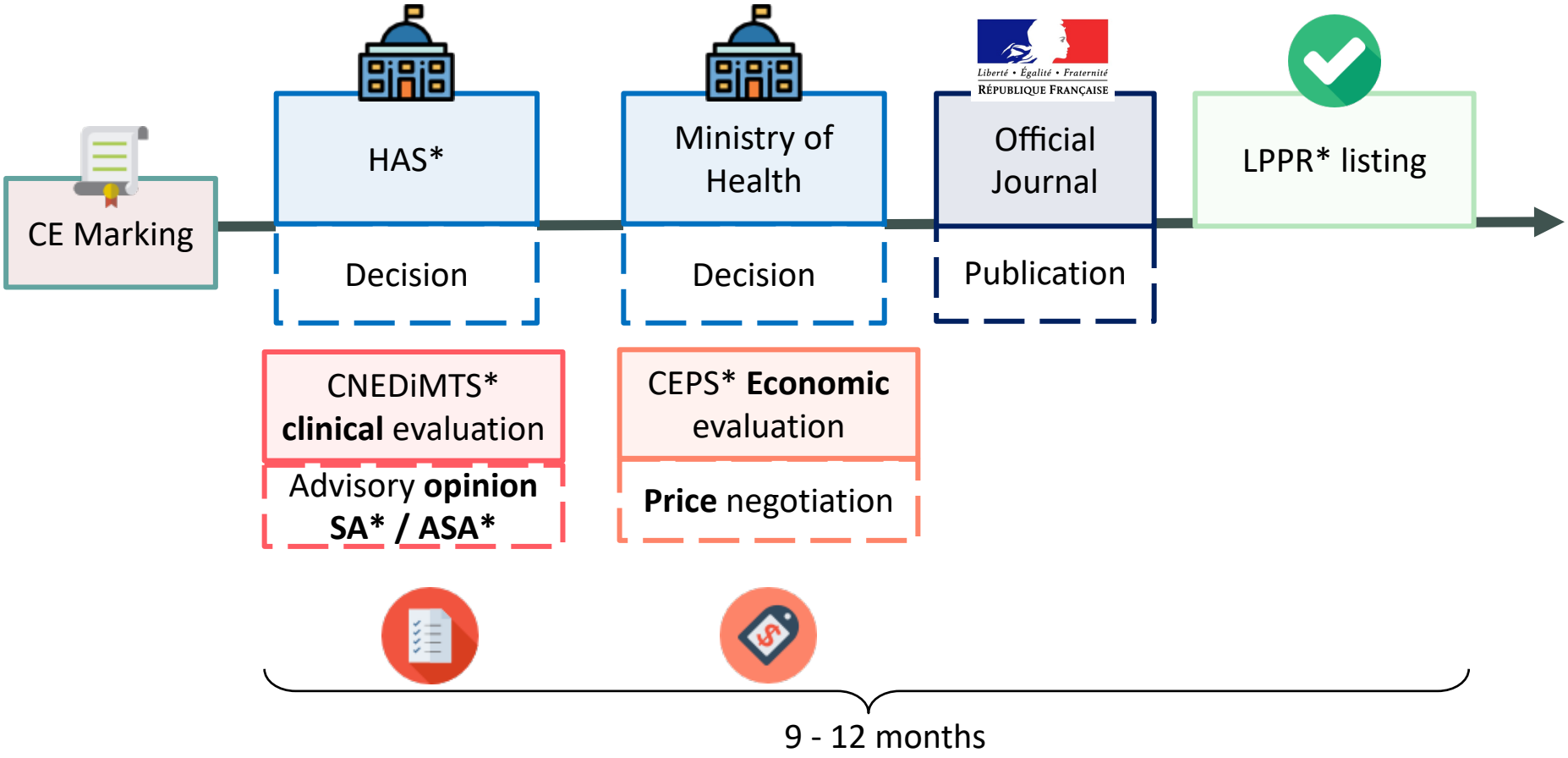
DRG* tariff
GHS *("Groupe Homogène de Séjour")*

*CCAM: Classification commune des actes médicaux *(Common Classification of Medical Procedures);* DRG: Groupe homogène de malades *(Diagnosis related group); ICD: Classification of Diseases;* MIGAC: Missions d'intérêt général et d'aide à la contractualisation *(Missions of general interest and contractual aid)*

2. Reimbursement with LPPR* listing

*LPPR: Liste des produits et prestations remboursables *(List of reimbursable products and services)*

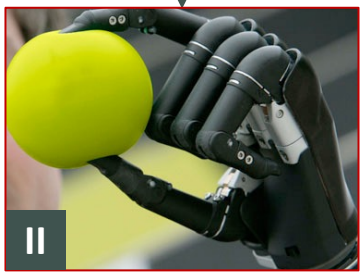
LPPR
Registration process (1/2)

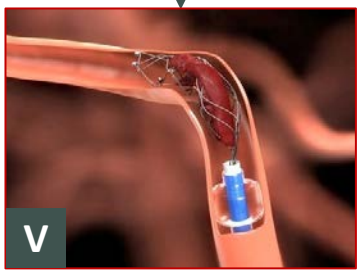


* ASA: Amélioration du Service Attendu (*Expected clinical added value);* CEPS: Comité Economique des Produits de Santé *(Economic Committee for Health Products);* CNEDIMTS: Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé *(Authority assessing medical devices);* HAS: Haute Autorité de Santé *(High Authority of Health);* LPPR: Liste des produits et prestations remboursables *(List of reimbursable products and services);* SA: Service Attendu *(Expected clinical value)*

LPPR
Registration process (2/2)

LPPR
List of reimbursable products and services





5 titles

Title I: Medical devices for life support, dietary foods and articles for dressings.

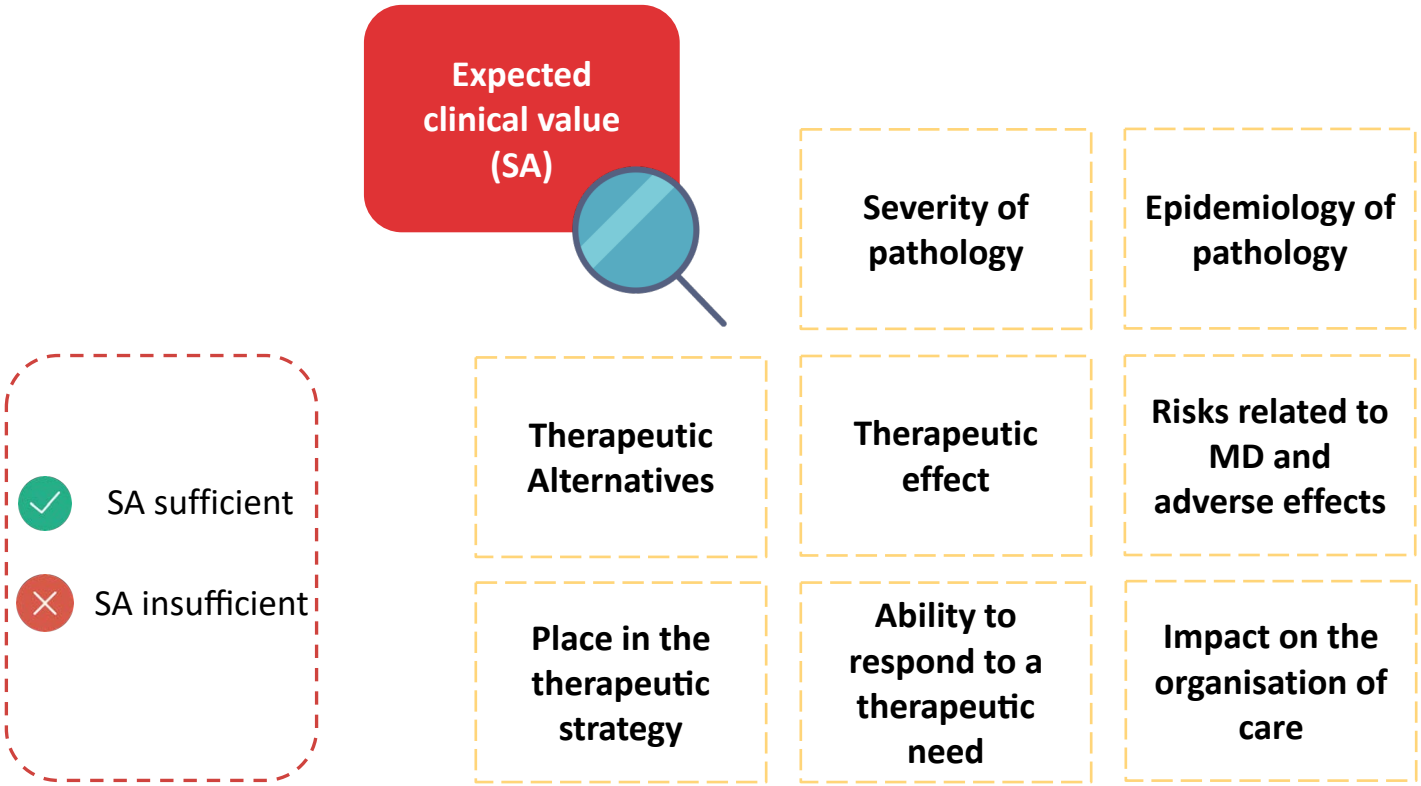
Title II: Orthoses and external prostheses.

Title III : Invasive medical devices, implants and tissue grafts of human origin.

Title IV: Vehicles for the physically disabled.

Title V : Invasive medical devices not eligible under Title III.

LPPR
HAS*: Expected clinical value



The expected service is measured by the clinical improvement of the patient's condition and is evaluated in each indication of the product or service.

* HAS: Haute Autorité de Santé *(High Authority of Health)*

LPPR
HAS*: Expected clinical added value

Expected clinical added value (ASA)

Which is the chosen comparator?

ASA I	Major
ASA II	Important
ASA III	Moderate
ASA IV	Minor
ASA V	Absent

What are the criteria for improvement?

Comparative study of sufficient methodological quality available?

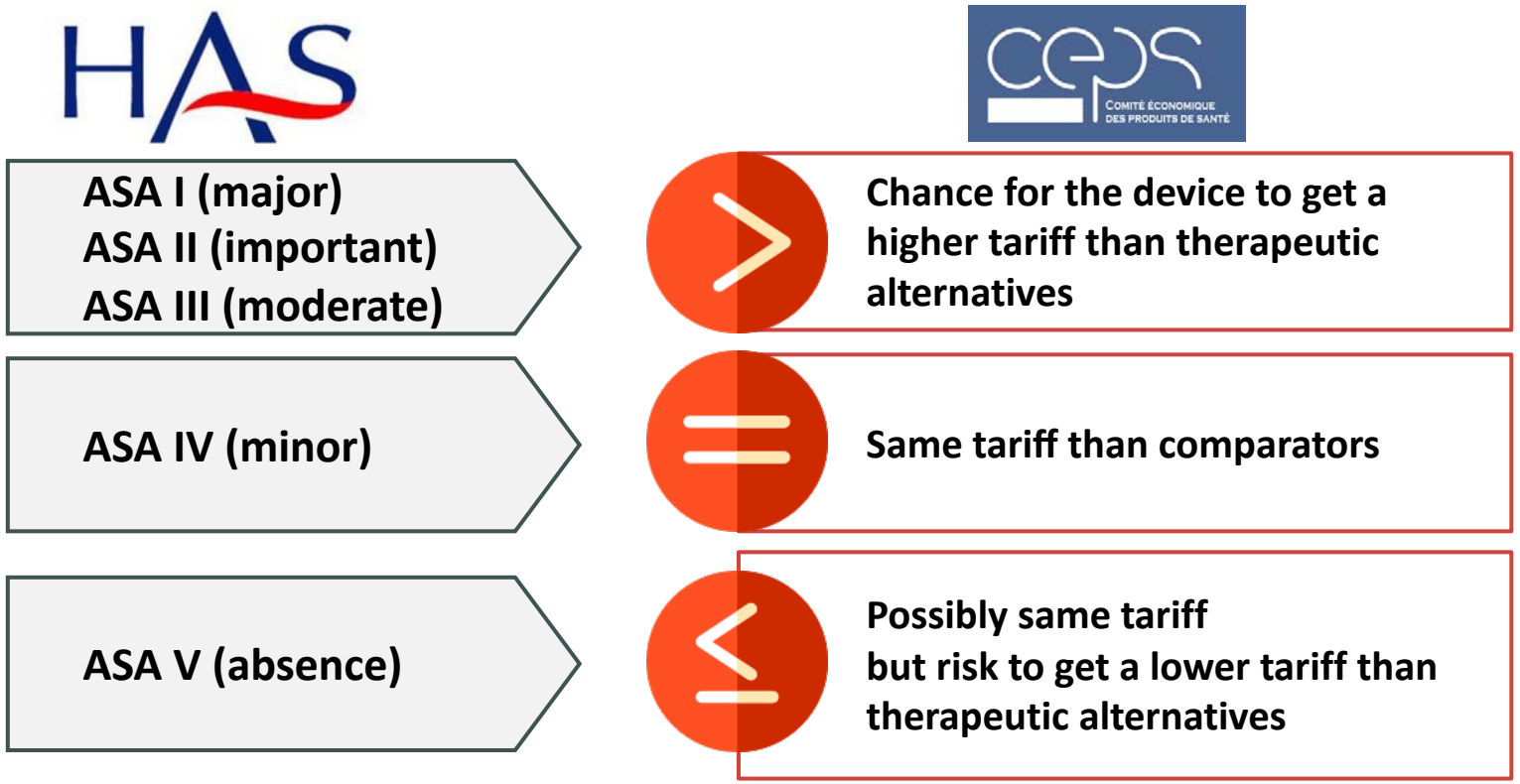
The improvement of the service expected is the measurement of the progress made compared to the reference treatment.

* HAS: Haute Autorité de Santé *(High Authority of Health)*

LPPR
Impact of the level of ASA* obtained on CEPS* pricing

Reimbursement is conditioned by a positive HAS* opinion (sufficient SA*).

Tariffs are quite related to the level of ASA* (*vs.* comparator) given by the HAS*.



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LPPR
How to demonstrate the value of the device?

The added value of a medical device is demonstrated by clinical trials.

Several types of clinical trials may be selected by the CNEDiMTS to analyze the efficacy and safety of the MD. However, a randomized controlled trial, when feasible, remains the gold standard.

Other types of clinical trials can be used and are sufficient to obtain reimbursement (comparative or not, multicentric or not, prospective or not). In order to determine whether the clinic affiliated with a MD is sufficient, it appears necessary to carry out a dedicated literature review.

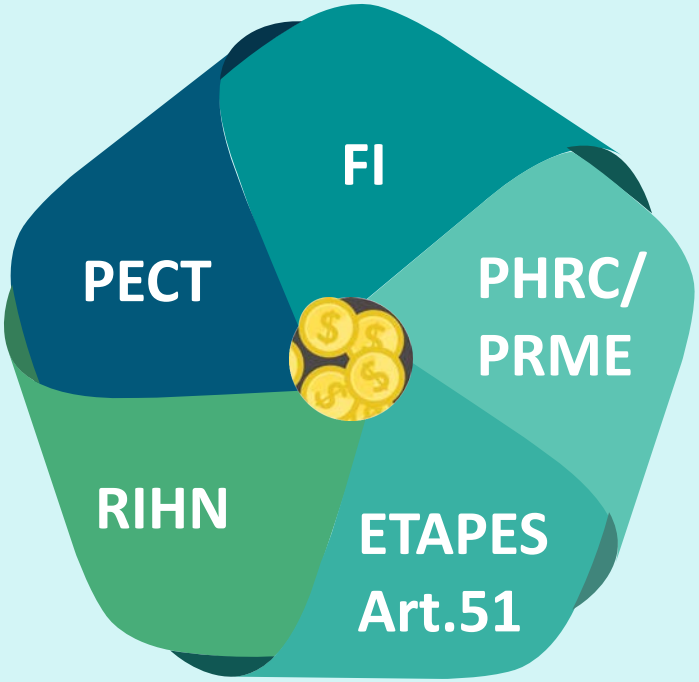
In all cases, certain elements appear to be key, such as the choice of:

- The main objective of the study;
- The different outcomes (primary and secondary criterias);
- Patient inclusion criteria;
- The comparator;
- The investigating centers.

What are the alternative funding pathways ?

Innovation Package

Early access (« Prise en charge transitoire »)

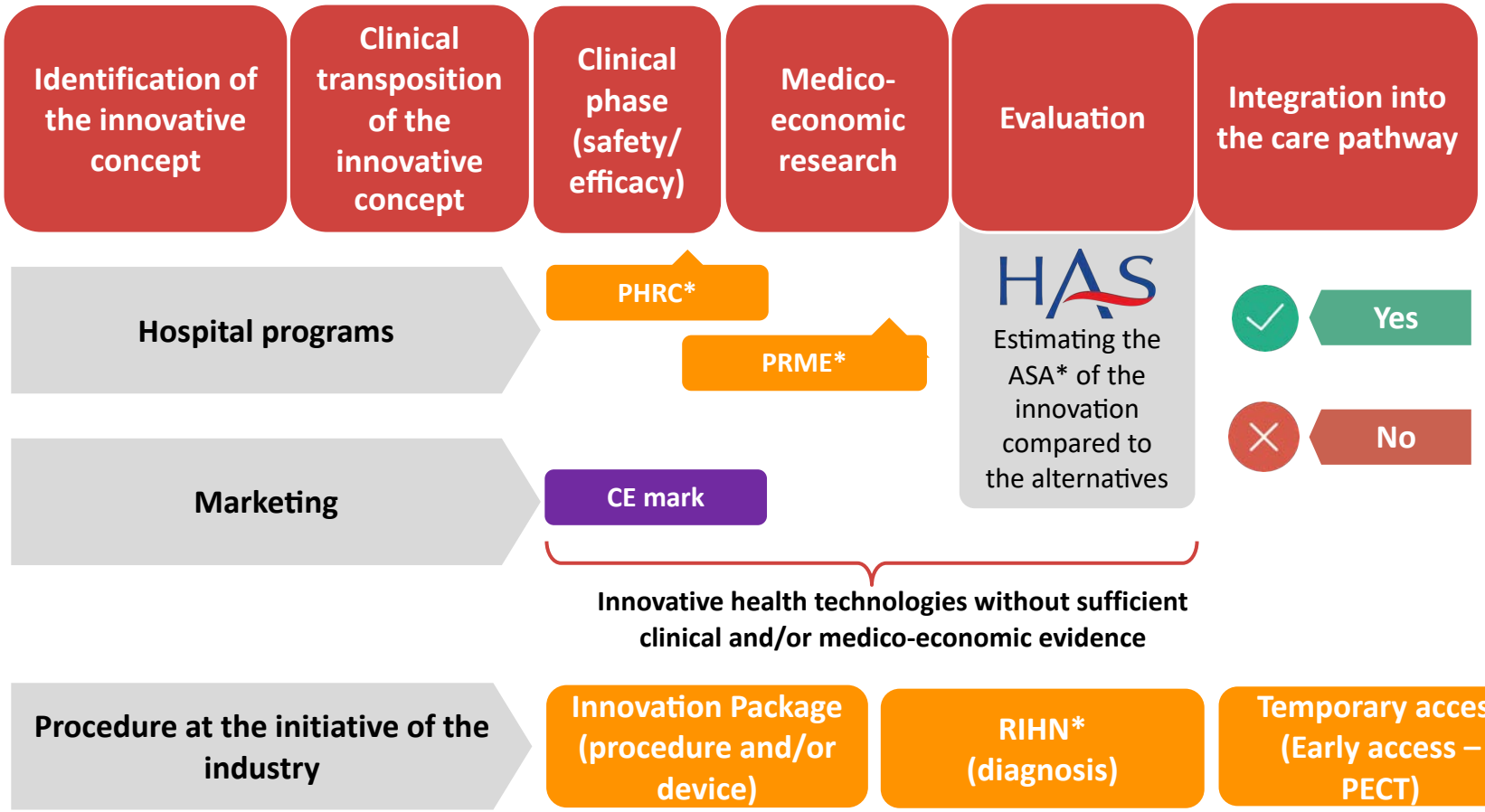


Hospital clinical research program/ Medico-economic research program

Framework for innovative non-nomenclature procedures

Telemedicine & Organisational Innovation

Innovation funding
Technology development continuum



The Ministry of Health manages **large projects** to **fund research teams** through **national calls for projects** that take place at **different stages** of the research.

* ASA: Amélioration du Service Attendu (*Expected clinical added value);* HAS: Haute Autorité de Santé *(High Authority of Health);* PHRC: Programme Hospitalier de Recherche Clinique (*Hospital Clinical Research Program);* PRME: Programme de Recherche Médico-Economique *(Medico-Economic Research Program);* RIHN: référentiel des actes innovants hors nomenclature de biologie et d'anatomopathologie *(reference system for innovative non-nomenclature biology and anatomopathology procedures)*

3. Innovation funding

Innovation funding
Innovation Package : Definition

Objective: to fund an innovation (MD, diagnostics, medical procedure) until it is reimbursed on a permanent basis (LPPR*/CCAM*).

Condition: Set-up of a new clinical study comparing the innovation to the clinical practice/gold standard treatment.

Implementation modalities: creation of a temporary hospital stay (DRG*) dedicated to the innovative technology.

*CCAM: Classification commune des actes médicaux *(Common Classification of Medical Procedures);* DRG: Groupe homogène de malades *(Diagnosis related group);* LPPR: Liste des produits et prestations remboursables *(List of reimbursable products and services)*

Innovation funding
Innovation Package : eligibility

A product/procedure is eligible when:

It is innovative

- Novelty
- In early diffusion stage, with insufficient evidence to justify public financing
- Safety profile assessed from available clinical trials
- Important clinical benefit *or* reduced healthcare costs are expected

The clinical trial or health economic study design is considered relevant

- Brings together necessary missing data
- Ongoing and expected studies have been identified
- The study feasibility appears to be reasonable regarding the protocol and the projected budget

Innovation funding
Innovation Package (IP) : application

IP dossier must be submitted to the health authorities.
It is divided into three parts.

The following elements must be provided.

A rationale justifying eligibility for IP

A complete study protocol

An estimated budget for the study

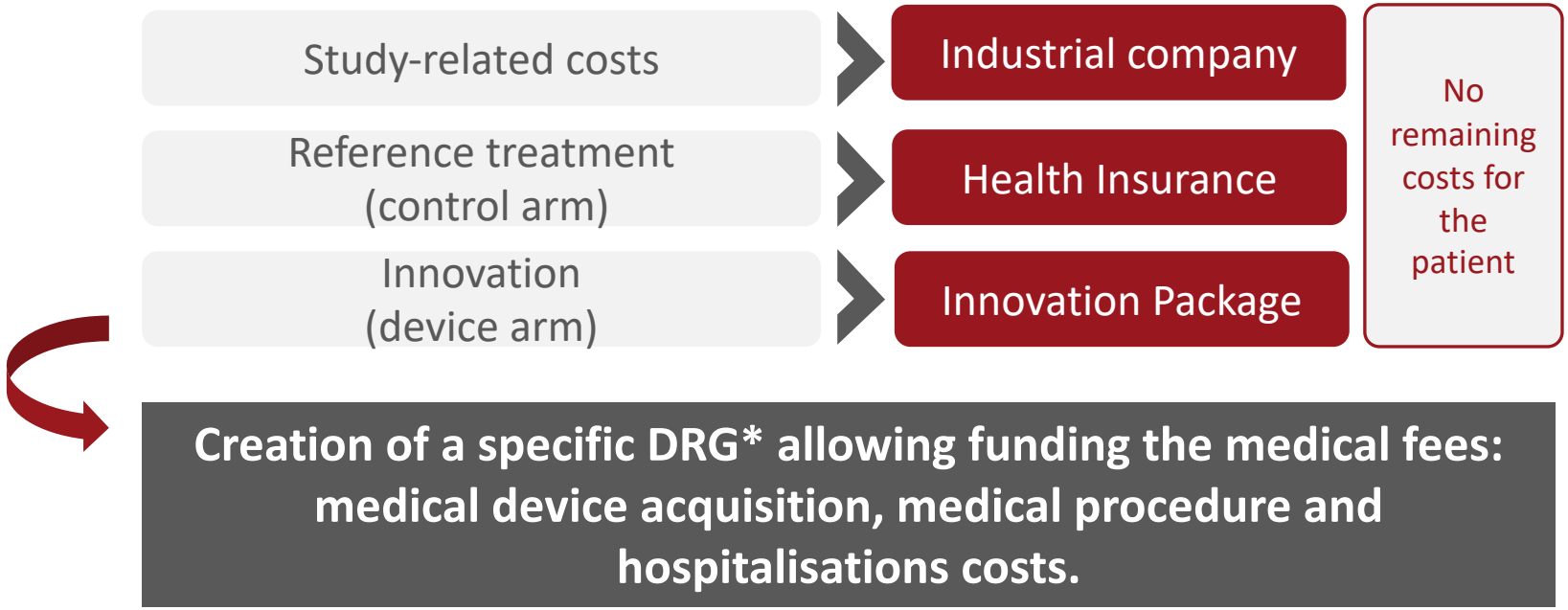
Built in coordination with…

Key Opinion Leaders (KOLs)

Contract Research Organization (CRO)
Principal Investigator (PI/co-PI)

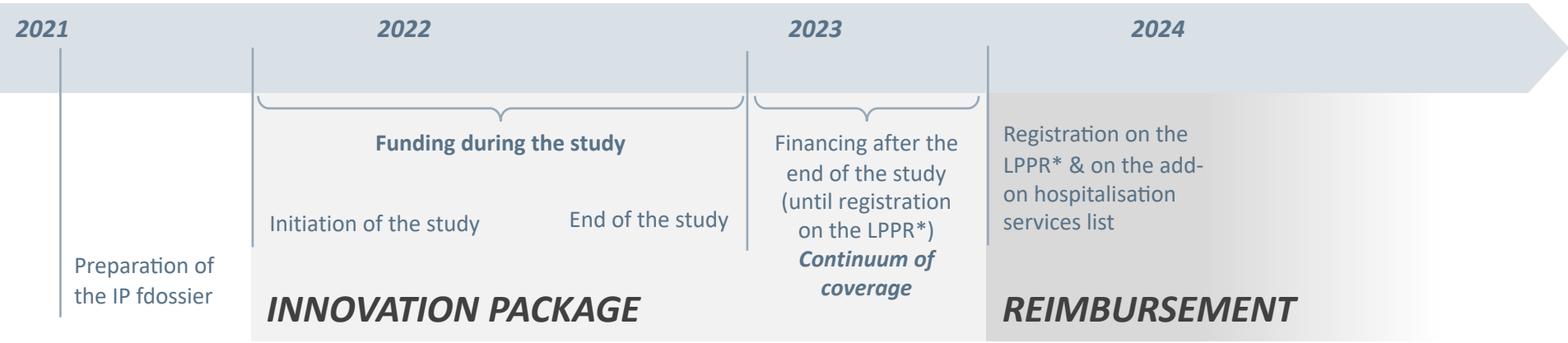
DRCI (hospital clinical research office)
Contract Research Organization (CRO)

Innovation funding
Cost-sharing within the Innovation Package



*DRG: Groupe homogène de malades *(Diagnosis related group)*

Innovation funding
Process of the Innovation Package



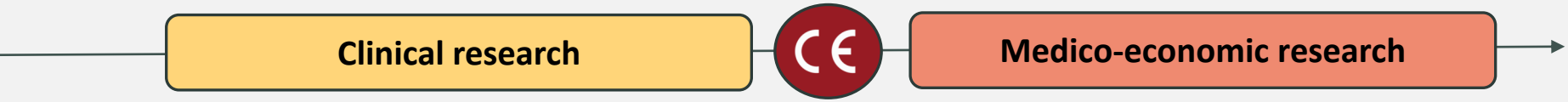
1 **Inclusion phase:** period of inclusion of patients in the study

2 **Continuous access phase:** extension of coverage to a larger number of patients (defined a priori with the health authorities), until permanent reimbursement/common law is obtained.

*LPPR: Liste des produits et prestations remboursables *(List of reimbursable products and services)*

Innovation funding
Hospital Research programs : PHRC & PRME

The PHRC and the PRME are two research programs for the development of technological innovations.
They work at different stages of development of the medical device:



PHRC
Hospital Clinical Research Program

PRME
Research Program of Medico-Economic

Innovation funding
PHRC: Objectives

Purpose of financing

- They cover all study-related costs, with the exception of the medical device itself. The medical device may be partially funded if CE marked.

Objectives of funded projects

- Measuring the effectiveness of health technologies, for this purpose, the research primarily funded are those that will contribute to obtaining recommendations of high grade;
- Evaluation of the safety, tolerance or feasibility of the use of health technologies in humans.
- The results of the projects should make it possible to directly modify the care of the patients.

Projet direction
A MIGAC eligible hospital out a learned society (the manufacturer does not have direct control of the study)

Funding
Maximum 4 years through the DGOS

Application
2 files to provide : A letter of intent and the study protocol

Location
Possible inclusion of European centers in addition to French centers (French principal investigator)

Validated projects
The PHRC was granted for 97 applications in 2017.

Frequency
Call for tenders once a year (deadline for submitting letters of intent generally in March)

Note: The PHRC may include a medico-economic component.

Innovation funding
PHRC : eligibility criteria

Justify the **direct impact** of the expected results on the management of patients

Demonstrate that research **methods** will provide data with a **high level of evidence**

3 categories

National « PHRC-N »

Cancer « PHRC-CK »

Inter-regional « PHRC-R »

Innovation funding
PRME : Objectives

Objective of the funding

- Facilitate and accelerate the evaluation of innovation (carried out by the HAS).
- Enable access to organisational innovation for a selection of costly innovations

Objectives of the funded projects

- Comparative studies to validate the clinical and medico-economic utility of innovative techniques
- Validate the efficiency of health technologies with a view to evaluation by the HAS
- Compare the efficiency of alternative management strategies in real life in order to optimise care.

Care pathways & health innovations

2 axes

2 years - Intended to cover the additional **costs** generated by the innovation.

Funding

Close follow-up of the project by the DGOS

Follow-up

In 2016
9 projects - €7 million

Key figures

Tender twice a year

Frequency

2 steps : A letter of intent and then a complete file

Selection

Innovation funding
PRME : eligibility criteria

Validation of the efficiency and estimation of the budgetary impact in a second phase in comparative clinical studies

- Efficiency measurement: analysis of production costs and **clinical utility** conducted in controlled trials, ideally randomised
- **Outcome criteria** assessing clinical utility must be **clinical**
- **Comparator** corresponding to the reference strategy

- Efficiency measurement based on **production cost** analysis **and real-life clinical utility ana**lysis
- **Budget impact analysis** required

First diffusion, market access or marketing phase and need for **CE mark**

3 categories

National

Cancer

Thematic

Innovation funding
PRME : Selection, funding and follow-up

Selection

2 steps

1. Pre-selection based on letters of intent → by an institutional panel
2. Selection on the basis of complete files → by a committee of experts

Funding

3 tranches

M0	25% Project initiation
M6	50% Start of the project
M24	25% On receipt of the final report

Follow-up

Close follow-up of the project by the DGOS

Publication of progress and final reports for each project

Funding to cover the extra cost incurred by the innovation...

... and not to change the sources of funding.

Innovation funding
Early access (PECT) : definition

Principle of the PECT

- **Intermediate fast-track procedure** between the Innovation Package and the standard procedures for registration on the LPPR - Temporary **full reimbursement** pending permanent coverage under the LPPR.

Objectives

- To facilitate rapid access to innovative technologies and medical devices;
- To respond to a medical need that is not covered or is poorly covered; serious or rare diseases or to compensate for a handicap;
- To enable the company to finalise a study and obtain specific clinical data.

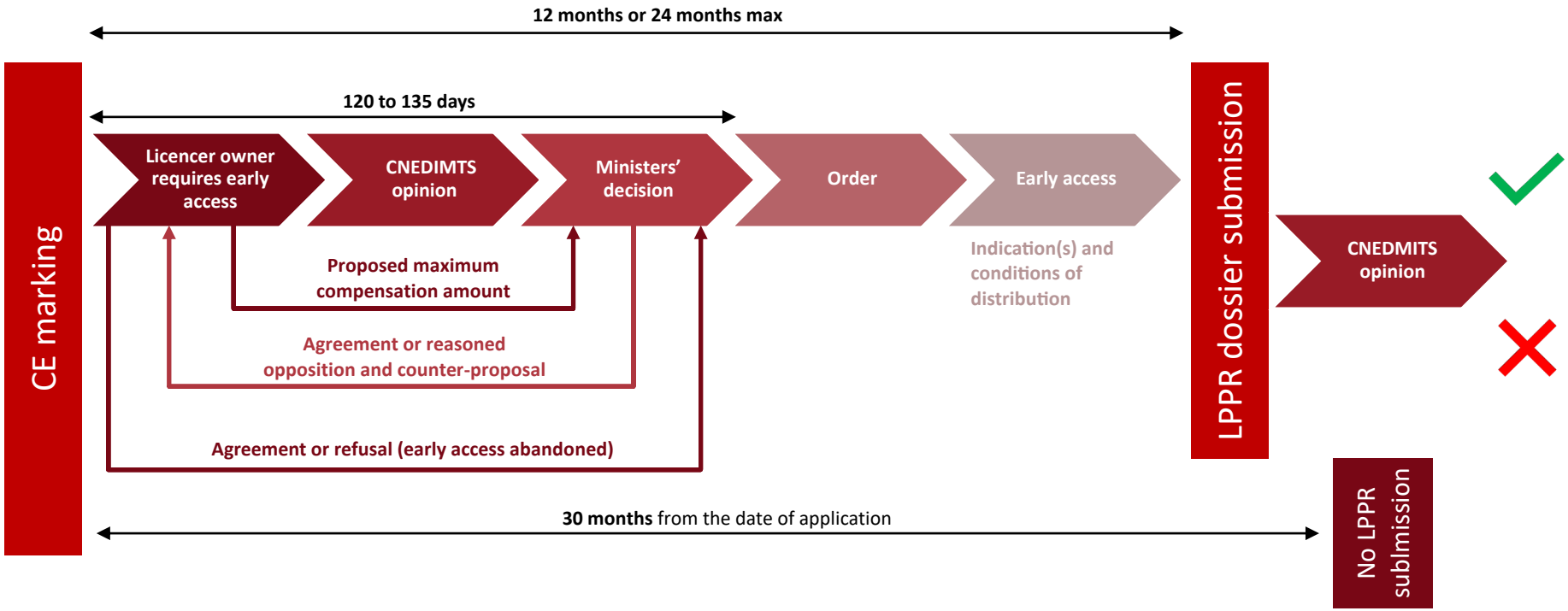
Prerogatives for a PECT

- CE marking;
- No reimbursement in the context of hospital services;
- Application for registration on the LPPR within 12 months of the PECT application;
- Ensuring continuity of treatment.

Benefits

- Accelerated reimbursement procedure: **< 5 months**;
- No price negotiation. However, the company may pay the difference between the PECT rates and the final reimbursement LPPR rate for the technology;
- **MTAC is a pioneer in the writing and submission of PECT dossiers, with success in 2021 (very first).**

Innovation funding
Early access (PECT) : A new temporary pathway



* CNEDIMTS: Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé *(Authority assessing medical devices)*

Innovation funding
Early access (PECT) : Eligibility criteria assessed by the CNEDiMTS

1. Treatment of a **serious or rare** disease or compensation for a disability.
2. **No relevant comparator**/therapeutic alternative.
3. **Significant improvement** in health status or compensation for disability.
4. Genuine innovation, **novelty**.
5. **Clinically relevant** efficacy and acceptable potential adverse effects.

Innovation funding
Milestones of the PECT process

One example of timeline, for someone who wants to submit an early access dossier

- Q1 2022: **Writing of the dossier + submission**
- Q1-Q2 2022 (5 months): **Process** of obtention of PECT
- **Anticipate the submission of an LPPR dossier** one year after submission

Innovation funding
Examples of PECT 1/2

The very first Medtech early transitional funding (PECT)

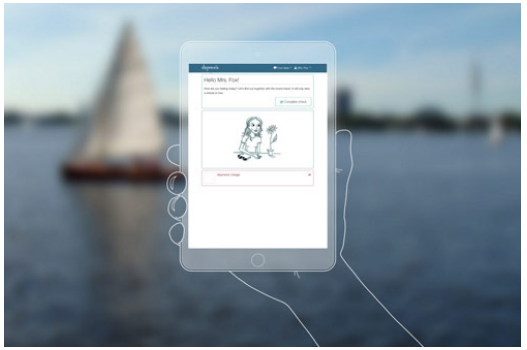
NEOVASC REDUCER System (Coronary sinus reduction system)

- **Positive HAS opinion** 42 days after the complete application
- **Published in the JO on March 07, 2022** 142 days after the complete application

Innovation funding
Examples of PECT 2/2

deprexis®

(Digital therapy for depression)



Unfavourable HAS opinion in 26 days after the complete request

HAS
HAUTE AUTORITÉ DE SANTÉ

- ✗ 1. Serious pathology only for depressive episodes of moderate to severe intensity
- ✓ 2. Can meet an unmet medical need
- ✗ 3. Not strongly likely to provide significant improvement in health status.
- ✓ 4. Is novel in nature other than a simple technical development
- ✗ 5. Not likely to provide clinically relevant efficacy and significant effect with respect to which their adverse effects are acceptable.

4. Focus on E-health

E-health & Medical Devices
Context

This part of the webinar aims to understand the options for a company wishing to market a connected medical device/e-health solution in France, in the context of a transition from the experimental program « ETAPES » (2017/2021) to « Common law » reimbursement scheme (from 2022)

TRADITIONAL PATHWAY

HAS
HAUTE AUTORITÉ DE SANTÉ

LPPR - List of products and services qualifying for reimbursement

INNOVATIVE PATHWAYS

étapes télémédecine

Telemedecine experiments

Art. 51 Innovation En santé

Organizational innovation experiments

Sustainable reimbursement

Temporary reimbursement

Common Law

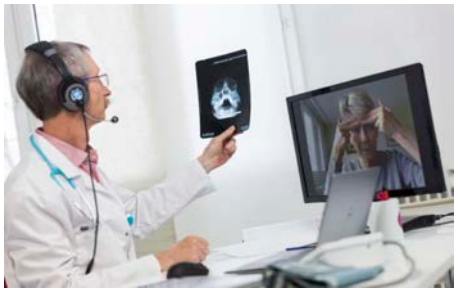
E-health & Medical Devices
Definition

- "e-health" covers a vast field of applications of information and telecommunication technologies in the service of health ;
- The HAS evaluates software for health professionals (prescription assistance software, electronic medical records, etc.), telemedicine (teleconsultation, tele-expertise, etc.), mobile health (health applications on cell phones) and user information.

Medical devices with artificial intelligence

Connected medical devices

Telemedicine



SPECIFIC FEATURES OF CLINICAL EVALUATION OF A CONNECTED MEDICAL DEVICE (CMD) - LPPR

CMDs eligible for evaluation by the CNEDiMTS meet the following four criteria.

1. They are **intended for use for medical purposes**, their end-use implying they are **CE-marked**.
2. They are for **individual use** (implanted or used by the patient themselves).
3. They have a **telecommunication function**.
4. The company **has submitted an application for reimbursement by national solidarity**.

The clinical development of a CMD must also take account of the features specific to CMDs :

- ✓ Very high **rapidity of technological development** ;
- ✓ **Interaction with other devices**/objects/platform (medical devices or other) ;
- ✓ Existence of **expert information processing systems** (such as programmed decision-making algorithms).

Source : Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement (HAS – January 2019).

KEY TAKEAWAYS OF CMD EVALUATION - LPPR

Four specific areas to CMD evaluation must be anticipated by the manufacturer or company operating the CMD:

1 An optimised clinical development programme

For all CMDs for individual use, the evaluation of their impact in terms of clinical benefit, acceptabilaity or improvement of quality of life for users is necessary. Other impacts can also be looked for, especially in terms of access to treatment, standard of care and organisation of care.

2 Prerequisites of any evaluation by CNEDiMTS

- ✓ *Requirements in terms of processing and hosting of data covered by applicable legislation, especially the GDPR;*
- ✓ *CE marking;*
- ✓ *Elements set up by the company for ensuring the quality of the results.*

3 Algorithms/ automatic data processing

The CNEDiMTS is not responsible for evaluating the mathematical functioning of the model. *However, information is to be provided both on the way in which the algorithm was created (choice and selection of variables, model selection and learning, etc.) and on monitoring of the relevance of the algorithm created (regular verification, absence of bias, etc.). These points must be taken into account in the model design.*

4 Real-life data collection

As long as the technology is evolving, ***the CNEDiMTS can request that post- registration studies be set up****. These studies, paid for by the company manufacturing or operating the technological solution, are used in particular to confirm the benefit of the CMD in a real-life use situation.*

Source : Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement (HAS – January 2019).

EXAMPLE N°1 – DIABEO (SANOFI AVENTIS)- LPPR

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.

The solution was co-developed by the CERITD (non-profit clinical translational research), Voluntis (software company) and Sanofi Aventis.

Sufficient expected value (SA)

ASA IV (minor) VS Conventional care, i.e. a paper follow-up notebook with face-to-face medical consultations.

Indication :

Adult patient with type 1 diabetes (diagnosed more than 1 year ago) not controlled (HbA1C ≥ 8%) by basal-bolus insulin therapy administered by multiple injections or pump (for at least 6 months).

The DIABEO Solution is reserved for patients who have received specific training in its use.

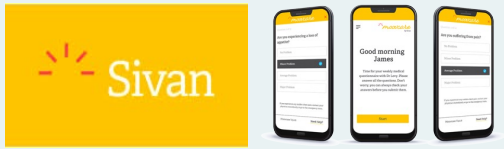
The type 2 diabetes indication was not retained.

Clinical evidence :

- ✓ **1 multicentre RCT, TELEDIAB1,** evaluating 180 patients at 6 months;
- ✓ 1 post-hoc analysis of the TELEDIAB 1 study;
- ✓ 1 observational study evaluating 35 patients at 17 weeks.

Source : DIABEO – CNEDiMTS OPINION (12/07/16).

EXAMPLE N°2 – MOOVCARE (SIVAN FRANCE)- LPPR



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

A Class I Medical Device, Moovcare® has been proven in clinical trial to improve overall survival by 7,6 months.

Sufficient expected value (SA)

ASA III (moderate) VS Conventional care only, i.e. follow-up by imaging and face-to-face medical consultations

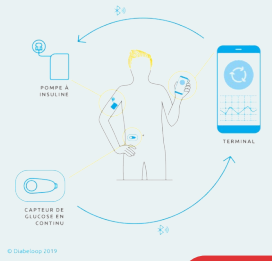
Indication :
Telemonitoring for the **early detection of recurrences or complications for patients over 16 years** of age with non-progressive lung cancer after evaluation of their last medical treatment irrespective of the historical type of tumour, in addition to conventional monitoring.

Clinical evidence :
- ✓ **1 multicentre RCT** evaluating 121 patients at 17,2 months;
- ✓ 1 comparative feasibility study evaluating 98 patients at 4,5 months;
- ✓ 1 non comparative feasibility study evaluating 43 patients at 5 months.

Source : MOOVCARE POUMON – CNEDiMTS OPINION (09/04/19).

EXAMPLE N°3 – DBLG1 SYSTEM (DIABELOOP SA) - LPPR

diabeloop



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

A Class IIb Medical Device, the DBLG 1 system consists of a mobile terminal and DBLG1 software (manufactured by Diabeloop), an external insulin pump KALEIDO (manufactured by Vicentra) and Dexcom G6 sensor and transmitter.

Sufficient expected value (SA)

ASA III (moderate) VS Open-loop systems consisting of an external insulin pump and an interstitial glucose sensor, operating independently

Indication :

Adult type 1 diabetic patients with poor glycemic control (HbA1c ≥ 8%) despite well-managed intensive insulin therapy under continuous subcutaneous insulin infusion (external pump) for more than 6 months and multiple daily self-monitoring of blood glucose (≥ 4/day).

Clinical evidence :

- ✓ **SP7 trial :** a cross-over, multicenter (12 centres), randomized controlled, open-label comparative study. 63 patients evaluated at 12 weeks ;
- ✓ SP6.2 study: a cross-over, multicenter (9 centres), randomized controlled, open-label comparative study. 42 patients évaluated at 3 days;
- ✓ 1 performance study (DBLG1-RD-2019)

Source : DBLG1 SYSTEM– CNEDiMTS OPINION (28/01/20).

5. Experimentations in telemedicine : the ETAPES programme

Experimentations in telemedicine

WHAT IS TELEMEDICINE ?

A remote medical practice (L.6316-1 CSP)

1 medical act performed by a medical professional (art 51 of the HPST law in 2009) in order to establish a diagnosis, ensure a follow-up, request a specialized advice or carry out a remote monitoring.

A **remote** practice :

- ✓ Using information and communication technologies ;
- ✓ Putting a patient in contact with a medical professional, if necessary through a medical assistant, or putting two medical professionals in contact with each other.

5 recognized medical procedures (R.6316-1 CSP)

- Tele-consultation
- Tele-expertise
- Telemonitoring
- Medical Tele-Assistance
- Regulation (centre 15)

Experimentations in telemedicine
ETAPES Program -Telemedecine: five medical procedures

Decree No. **2010-1229** of 19 October 2010 defines 5 types of medical procedures related to telemedicine:

Teleconsultation	Allows a medical professional to give a remote consultation to a patient.
Teleexpertise	Allows a medical professional to solicit the advice of one or more medical professionals from a distance, because of their particular training or skills.
Telesurveillance	To allow a medical professional to interpret remotely the data necessary for the medical follow-up of a patient and, if necessary, to make decisions relating to the care of this patient.
Teleassistance	Allows a medical professional to remotely assist another health professional during the course of performing a medical procedure.
Medical response	Call from the center 15.

Experimentations in telemedicine
ETAPES Program : Teleconsultation & Teleexpertise

- After 10 years of experimentation, the **orders of August 2018 approving rider No. 6 to the national agreement organizing relations between private practitioners and health insurance** signed on August 25, 2016, allowed for the reimbursement by Health Insurance of teleconsultation procedures in September 2018 and teleexpertise procedures in February 2019

- Tele-expertise and tele-consultation were widely used during the covid 19 crisis

- Experiments are maintained only for telesurveillance

Experimentations in telemedicine
ETAPES Program -Telemedecine: five medical procedures

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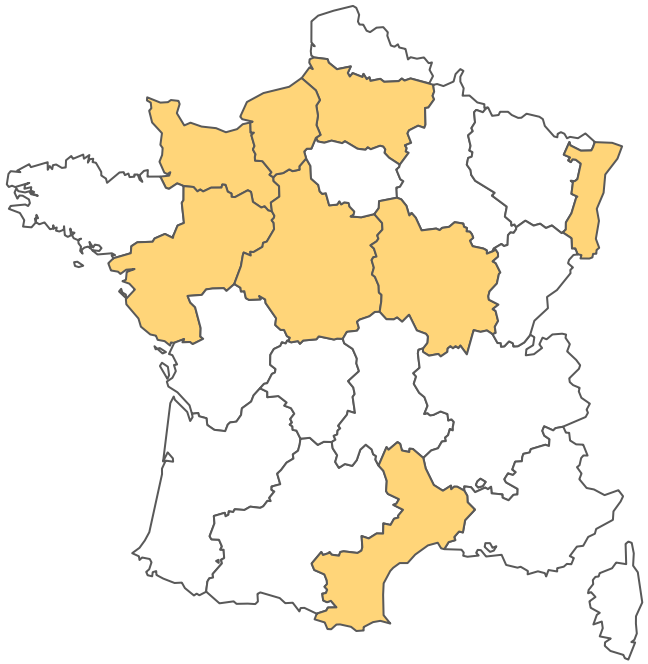
Experimentations in telemedicine

ETAPES Program - History of the program (1/2)

PLFSS* 2014, article 36

Experiments on the deployment of telemedicine can be conducted from 1 January 2014 for a period of 4 years, in pilot regions, the list of which is decided by the ministers of health and social security. These experiments concern the realization of telemedicine acts for patients in charge, on the one hand, in city medicine and, on the other hand, in medico-social structures ".

Actors: healthcare professionals – home healthcare providers - professionals carrying out the therapeutic assistance



French telemonitoring program

** PLFSS: draft law on the financing of social security*

Experimentations in telemedicine
ETAPES Program - History of the program (2/2)

PLFSS* 2017

Extension of the program to all the territory

One year extension of the experimental scheme (until December 2018)

PLFSS* 2018

Extension of the program until 2022

PLFSS* 2022

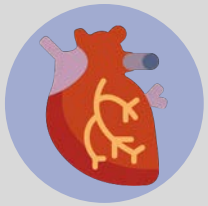
Establishment of a specific and permanent management procedure for telemonitoring activities (Transition to the common law)

** PLFSS: draft law on the financing of social security*

Experimentations in telemedicine
ETAPES Program - Scope of the program

The published telemonitoring specification reports, present an organisational and economical model for monitoring patients (long-term disease) affected by a **chronic disease** at home or in home substitues:

2016



Heart failure

Renal failure

Respiratory failure

2017

Diabetes

Implantable heart prostheses

Experimentations in telemedicine

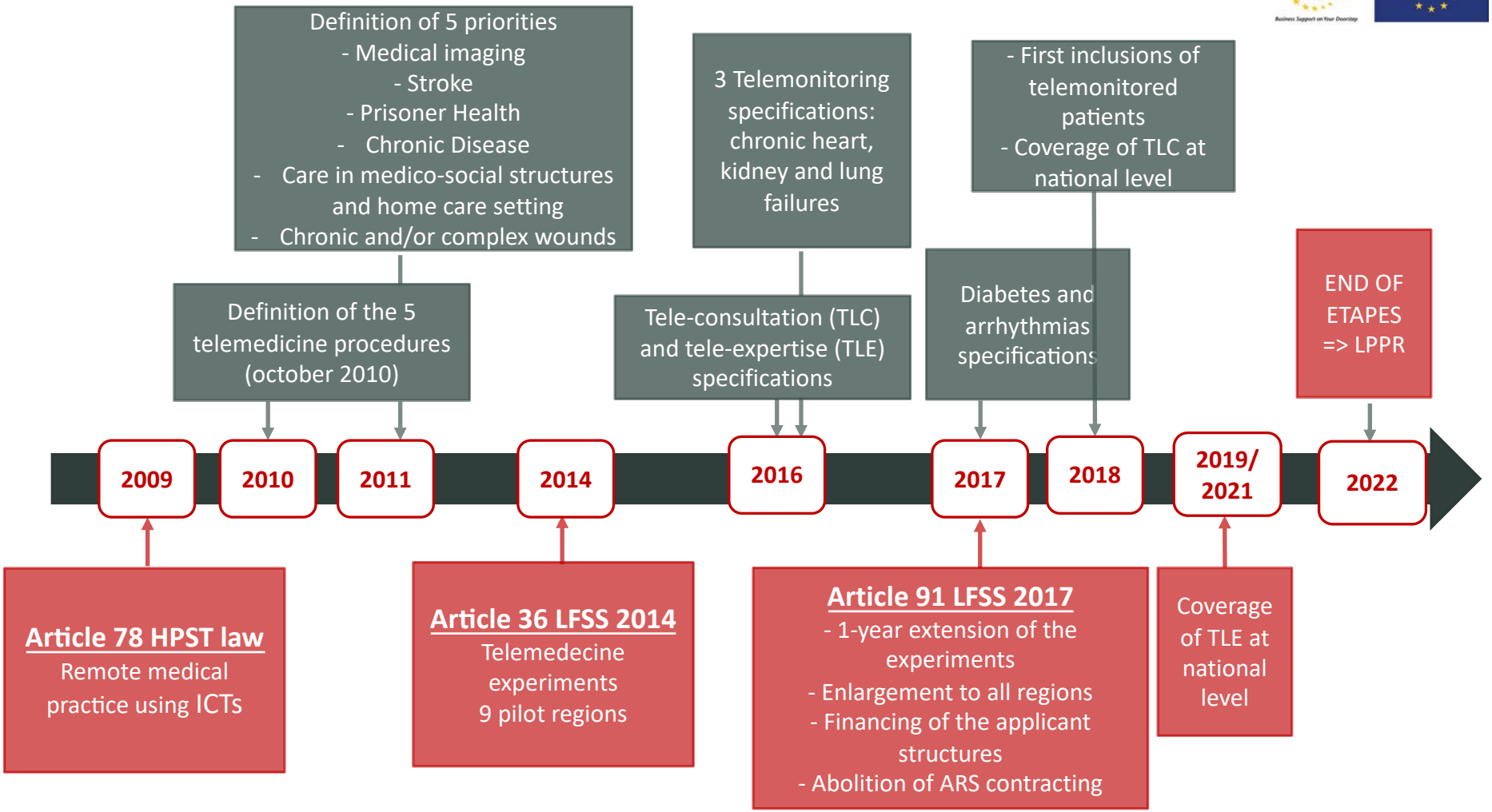
ETAPES Program - Four-step registration procedure

1	2	3	4
Declaration of conformity	**Statement of activities**	**Application for autorisation to process health data**	**Administrative documents**
Direction générale de l'offre de soins	Agence Régionale de Santé	CNIL.	l'Assurance Maladie

** ARS: Regional Health Agency; CNIL: National Commission for Information Technology and Civil Liberties*

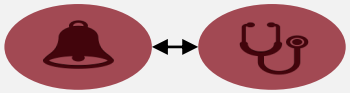
Experimentations in telemedicine : The ETAPES programme

ACCELERATING DEPLOYMENT OF TELEMEDICINE OVER THE LAST 10 YEARS



ETAPES programme

EXAMPLE: TECHNICAL SOLUTIONS IN DIABETES

myDiabby		Sends alerts to the doctor
diabeo		Sends alerts to the doctor + alert management by a platform
PROmed		Sends alerts to the doctor + alert management by a platform
CHRONIC CARE CONNECT		Sends alerts to the doctor + alert management by a platform

Experimentations in telemedicine : The ETAPES programme

Pre-requisites for the common law coverage of TLS

Compliance with interoperability and security standards (Convergence / Requirement)

Registration of the TLS activity on the TLS list (article 36 of the LFSS 2022)

For a transition to common law, there are **3 prerequisites** for registering a telesurveillance solution on the TS list entitling to reimbursement

1. CE marking
2. Compliance with the Convergence / Requirement - ANS standards
3. Compliance with the HAS standard corresponding to the pathology concerned

Experimentations in telemedicine : The ETAPES programme

Publication of HAS guidelines

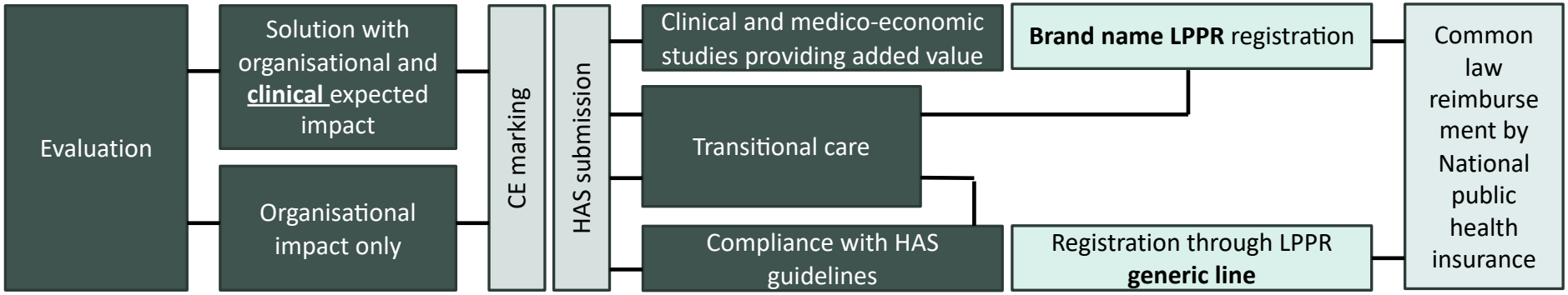
January 18, 2022 : Adoption of the standards by CNEDiMTS

- Four guidelines have been adopted:
  - ✓Chronic respiratory failure patients
  - ✓Chronic heart failure patients
  - ✓Chronic renal failure patients
  - ✓Diabetic patients
- Subsequent publication of the guidelines for the remote monitoring of patients with implantable cardiac prostheses for therapeutic purposes (adopted by the Cnedimts on March 1, 2022)

Experimentations in telemedicine : The ETAPES programme

Future evaluation process for remote monitoring

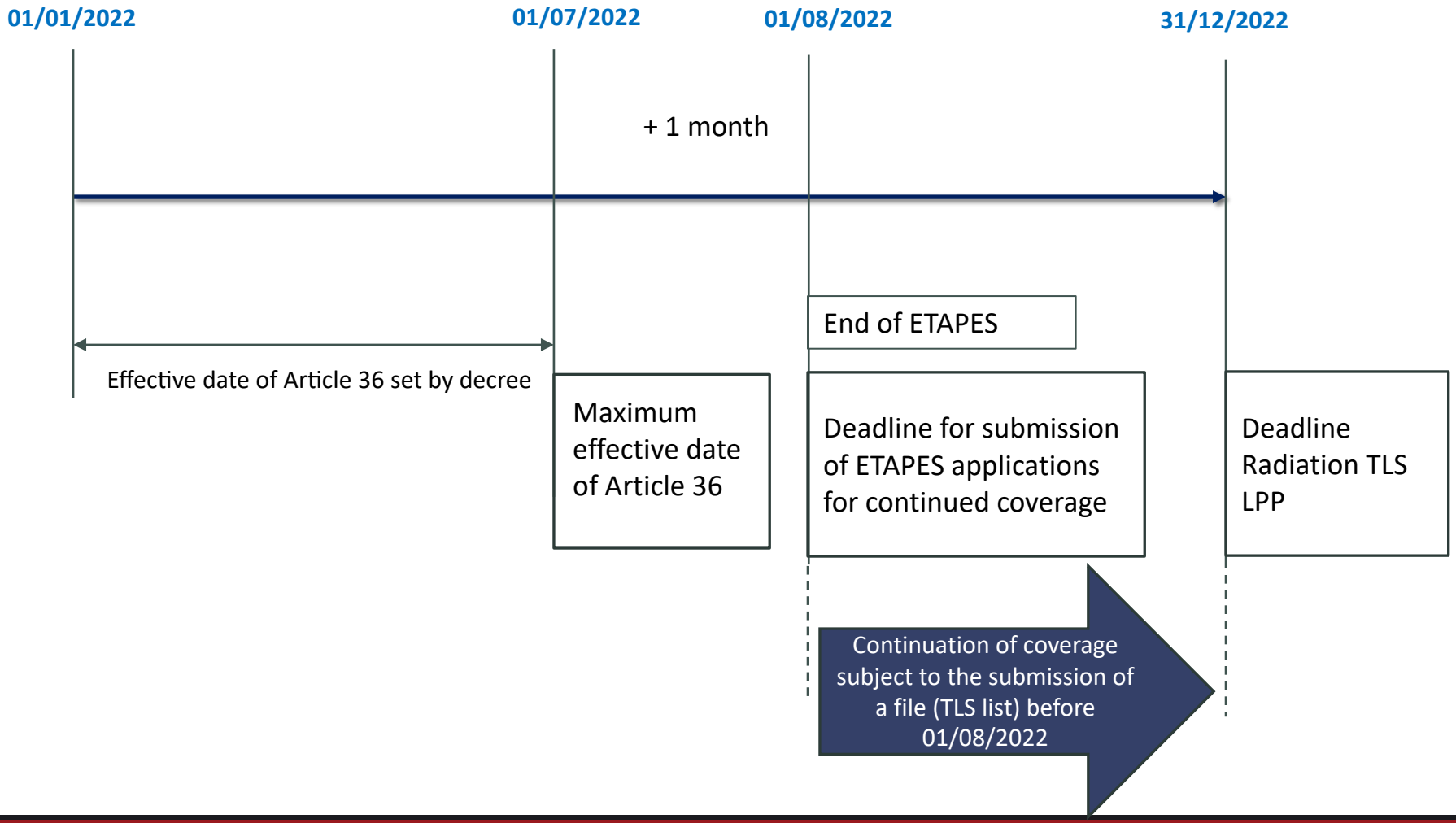
Focus on the process



Actors and remuneration

Actors	• Prescribers • Device companies
Remuneration model	• Flat-rate payment per patient for the solution

Experimentations in telemedicine : ETAPES programme
Transition of the **ETAPES Program** to common law



Experimentations in telemedicine : ETAPES programme
Conclusion

- Transition to common law

❑ HAS guidelines have been published

❑ Tariff negotiations almost finalized

❑ The timetable for the deployment has been set (1st step at the beginning of August, final exit from the experiment at the end of December 2022)

- Some questions remain

❑ Distinction between clinical and organizational impact

❑ Evaluation procedure by the CNEDiMTS

❑ Clinical impact on VAT rate

❑ Sustainability of the registration in common law

6. Go-To-Market

Go-To-Market

Why Go-To-Market in parallel to Market Access ?

Your top 5 tactical needs

1. Enhancing the probability to get reimbursement with a premium price in due time
2. Building-up a community of early adopters willing to commit as an influencing supporter
3. Optimizing the timeframe of reimbursement submission to setup a commercial pre-launch
4. Planning the full commercial setup by assessing the best sales/marketing option : local distribution vs direct sales team
5. Keeping control and agility without fix (heavy) costs and with full flexibility to accelerate and to slowdown whenever it is needed.

Why Go-To-Market Strategy ?

To work on the field and in full alignement with the market access strategy (MediTech Access) by dealing with kols, reference centers and academic stakeholders to raise support for reimbursement

However strong the clinical dossier is, French healthcare authorities are used to asking feedback to French early users in the process of making the decision about reimbursement

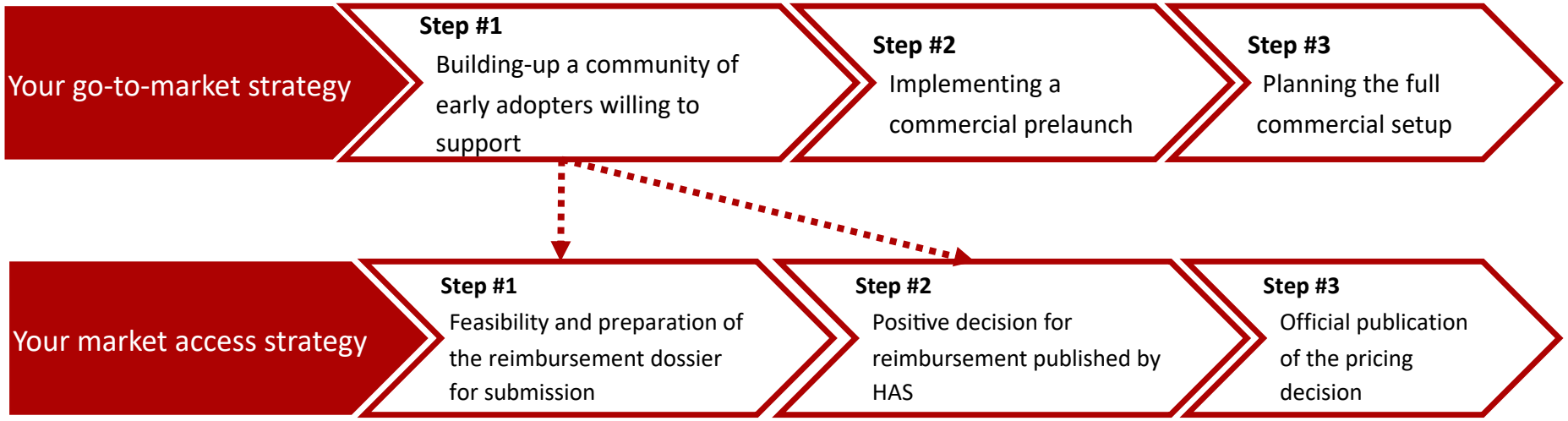
For innovative technologies, it would be necessary to trigger local funding in university hospitals to purchase devices awaiting reimbursement

To implement the best setup by identifying the potential partners / profiles at early stage in order to kickoff just after the announcement of reimbursement

At this early stage of market penetration, a full time employee based in France is NOT cost effective

Go-To-Market

Market Access with Go-To-Market : Full alignement & collaboration



Go-To-Market

Step by step roadmap with potential milestones on the field

Step #3

Planning the full commercial setup by advising on the best sales/marketing option

Full commercial launch

- Brainstorming on go to market options : direct vs distribution
- Scouting and hiring sales & clinical talents
- Managing third parties to set up a legal entity
- Searching distributors with a track record
- Negociating a distribution contract

Step #2

Implementing a commercial pre-launch

- Showing up in academic events (meetings, webinars)
- Facilitating publications of local guidelines & protocols
- Extending referrals funded locally
- Engaging and coordinating proctors
- Implementing a French registry endorsed by the local academic society
- Developing a platform of speakers
- Triggering local funding to purchase devices
- Building-up centers of excellence
- Enrolling French sites into international registries/studies

Step #1

Building-up a community of early adopters willing to commit as an influencing supporter

- Identifying potential early adopters
- Opening sites with first patients
- Creating a community of few early users
- Enhancing learning curve
- Approaching key opinions leaders
- Raising awareness among reference centers
- Early talking with local academic societies

Your market access strategy implemented by MediTech Access

Submitting for reimbursed price on LPPR / forfait innovation / early access (PECT) / new DRG code

→ Price of reimbursement on LPPR / FI / PECT / DRG code published in the Journal Officiel

HAS Commission Nationale d'Evaluation des Dispositifs Médicaux et Technologies de Santé (CNEDiMTS)

CEPS Comité Économique des Produits de Santé

CCAM Classification Commune des Actes Médicaux

République Française Journal Officiel Lois et Décrets

A Local + Global specificity

AiM

MEDITECH ACCESS

Device Access®
MARKET ACCESS. ACCELERATED

- Meditech Access has **a local vision in an international context,** in partnership with European partners.
- This partnerships allows us to deal with **National or European projects**: decrypting and scheduling key phases, global responses to all market access issues and pitfalls in Europe.

A six-part supply of services for European Market

STRATEGY AT LOCAL, NATIONAL & EUROPEAN LEVELS

PUBLIC AFFAIRS

PRICING & NEGOTIATIONS GO-TO-MARKET

MEDICAL WRITING

TRAINING

DUE DILIGENCE & BUSINESS DEVELOPMENT

Market Access pathways in France
Conclusion

- Progress has been made in recent years in the introduction of innovative technologies (early access mechanisms for innovative medical devices, implementation of the 2030 health innovation plan, widespread coverage of remote monitoring…) ;
- Innovations are currently being finalized: improved registration of procedures (High Council for Nomenclatures) ;
- However, much work remains to be done, particularly to simplify the reimbursement process for new technologies and reduce the time to market

Thank you!

Questions