

MICCAI 2013

Visual tracking and 3D reconstruction for computer-assisted interventions tutorial  
Sept 22, 2013 – Nagoya, Japan  
State-of-the-art and challenges

# TOWARDS A DECREASE OF THE DELAY BETWEEN LABORATORY INNOVATIONS AND THEIR CLINICAL EVALUATION

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# GRENOBLE?

9845km from NAGOYA



# GRENOBLE



# WHY BEING INTERESTED IN ACCELERATING THE TRANSFER FROM LABORATORY TO CLINICAL SETTING ?

## ***Computer Assisted Medical Interventions (CAMI)***

- *Improvement of the care* delivered to our patients
  - Added-value? Demonstration?
- *Innovative Technology (Medical Device - MD)*  
Many innovations in the field
  - Drug  $\approx$  10 patent // MD  $\approx$  2000 patents
    - Short to enter the market
- *Usability : MD use  $\neq$  Drug Use*



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NEED TO TAKE INTO ACCOUNT THE  
***PARTICULARITIES*** OF THE MEDICAL  
DEVICES  
TO IMAGINE NEW APPROACHES FOR  
ACCELERATING THE ESTIMATION /  
DEMONSTRATION OF  
ITS MEDICAL SERVICE



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# A MEDICAL SERVICE... for a MEDICAL DEVICE ?

**Medical service** associated to a medical device :

How the medical device **is contributing** to :

- the **improvement** of the care of a patient
- The **improvement** of the care of a population of patients





# TALK OUTLINE

I - Formalization of the maturation cycle of a *Medical Device*

II - Formalization of the maturation cycle of the *Medical Service*

III - Examples of acceleration of the *demonstration* of the Medical Service



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# TALK OUTLINE

I - Formalization of the maturation cycle of a ***Medical Device***

II - Formalization of the maturation cycle of the ***Medical Service***

III - Tools for accelerating the ***demonstration*** of the Medical Service



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# The Grenoble Experience

Augmented surgery in Grenoble:  
a serie of premieres

Prostate Biopsy 3D  
reconstruction  
Dr Mozer, Pr Richard



2006

Compact motorized scope holder for  
advanced laparoscopic surgery  
J-L Descotes, J-J Rambeaud, C Létoublon,  
F Richard, P Mozer



2003

MRI/sonography fusion for prostate  
curitherapy  
Pr Bolla, Dr Fournieret, J.Y. Giraud,  
Pr Descottes

Robotized TeleEchograh  
G. Ferretti, I. Bricault, J-J Banihachemi



2000

Navigation of Total Knee Prothesis  
Pr. D. Saragaglia

1999

Navigation of vertebral pedicular screws  
Pr. Ph Mertoiz



1997

Navigation of Knee Ligamentoplasty  
Dr. R. Julliard

1995

Navigation of Orthognatic surgery  
Pr. B. Raphael



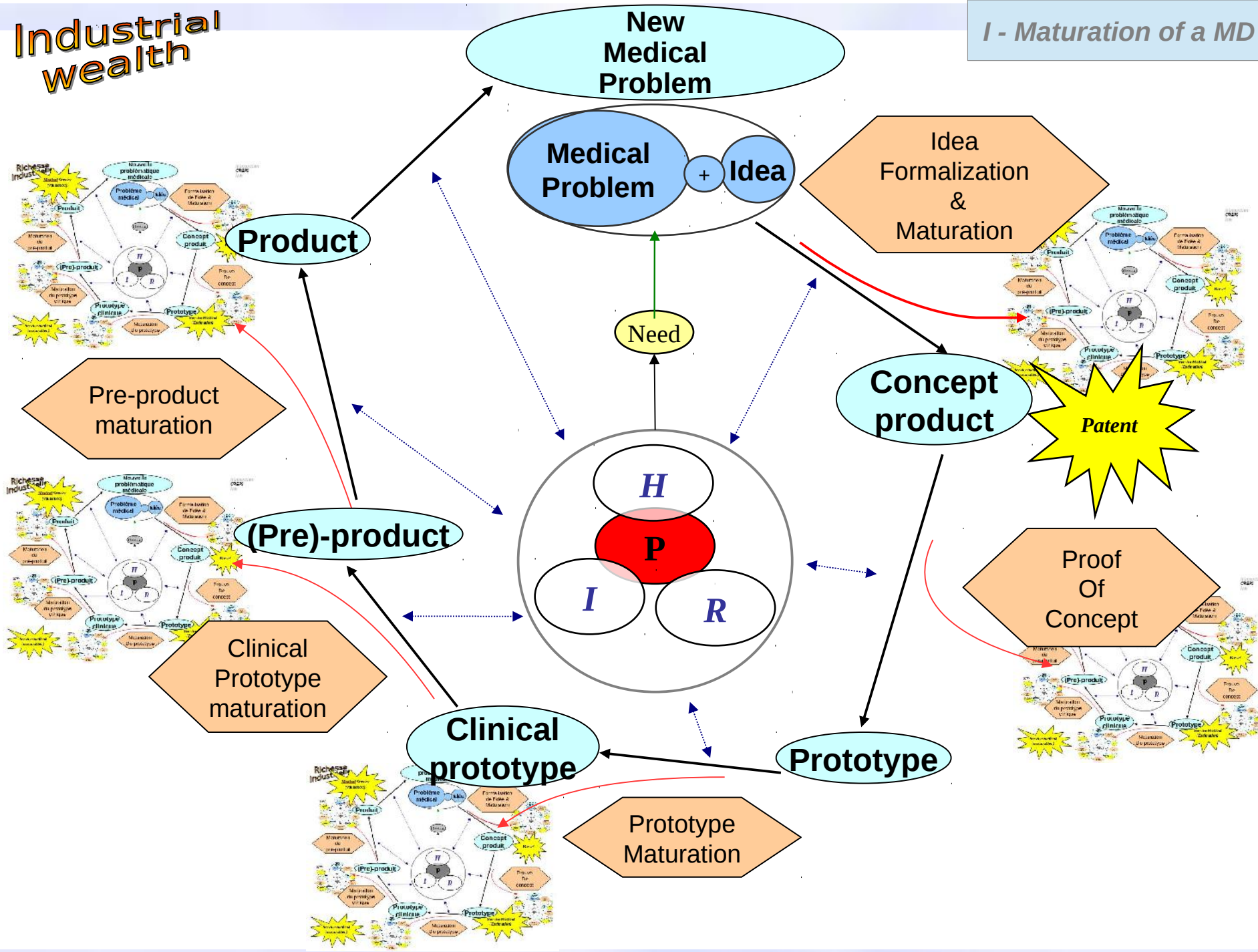
1989

Robotized Brain Stereotaxic Surgery  
S. Lavallée, Pr. A L Benabid

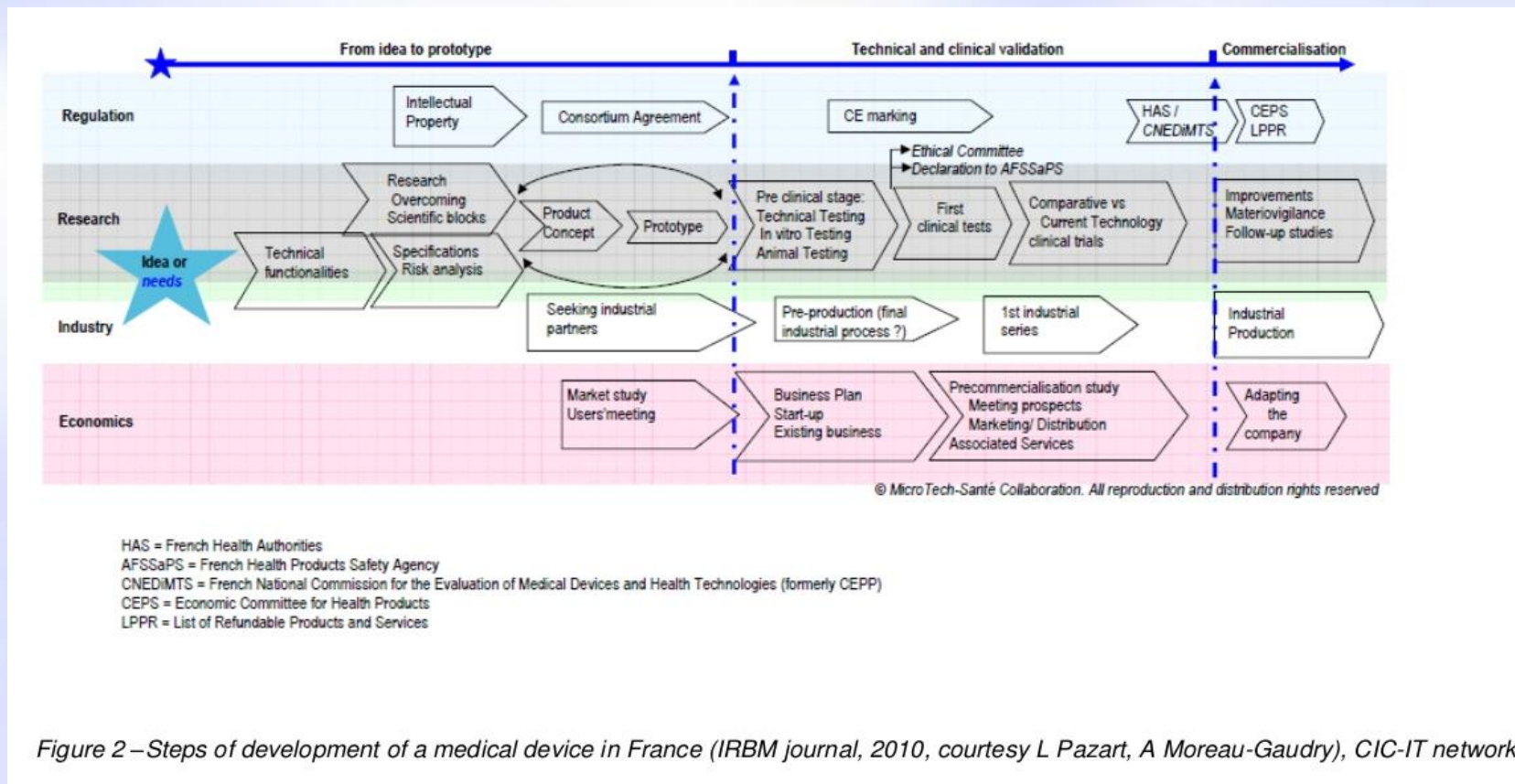


Industrial wealth

I - Maturation of a MD



# OTHER REPRESENTATIONS



HAS = French Health Authorities  
 AFSSaPS = French Health Products Safety Agency  
 CNEDIMTS = French National Commission for the Evaluation of Medical Devices and Health Technologies (formerly CEPP)  
 CEPS = Economic Committee for Health Products  
 LPPR = List of Refundable Products and Services

Figure 2 – Steps of development of a medical device in France (IRBM journal, 2010, courtesy L Pazart, A Moreau-Gaudry), CIC-IT network



# IDEAL approach

## *No surgical innovation without evaluation: the IDEAL recommendations*

Peter McCulloch and all. Lancet 2009

- Stage 1: **I**nnovation (Proof of concept)
- Stage 2a: **D**evelopment
- Stage 2b : **E**xploration (Learning)
- Stage 3: **A**ssessment (Assesment)
- Stage 4: **L**ong-term study (Surveillance)



# Maturation cycle of a medical device

*Maturation cycle of  
an Innovative Technology in Health*

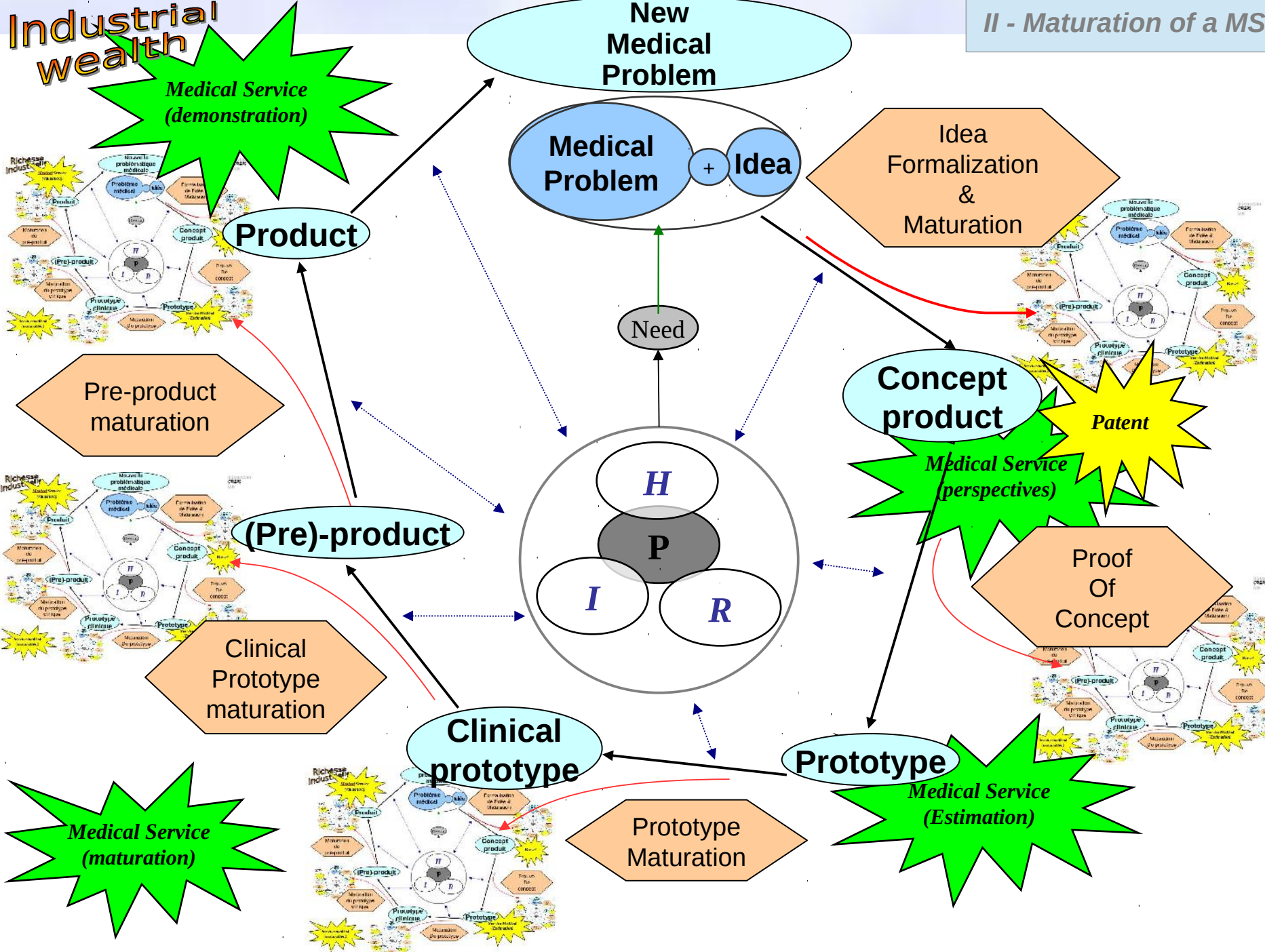


Maturation cycle of the **MEDICAL SERVICE**  
of an Innovative Technology



**Industrial wealth**

*II - Maturation of a MS*





Industrial wealth

Medical Service (demonstration)

New Medical Problem

Medical Problem + Idea

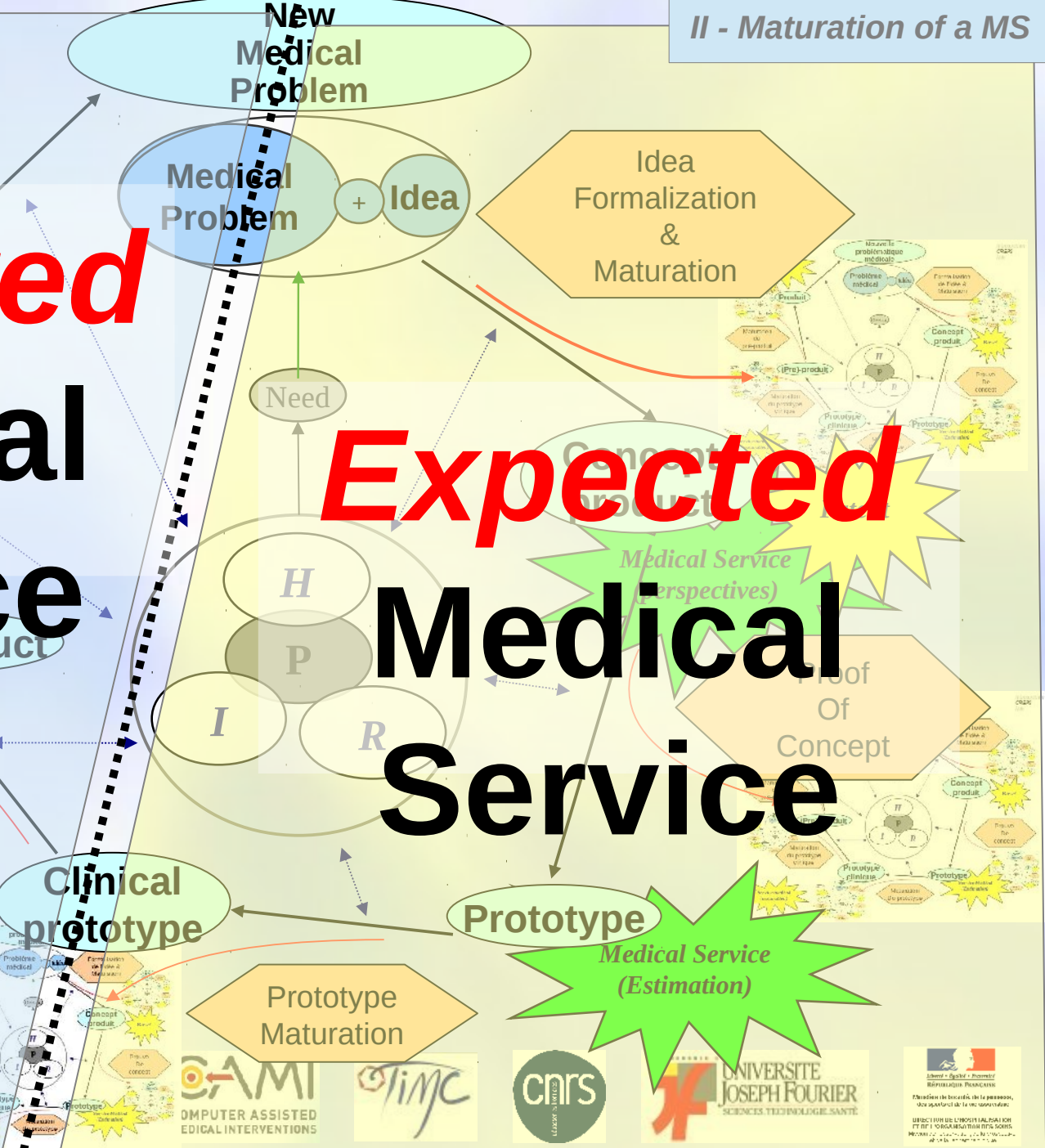
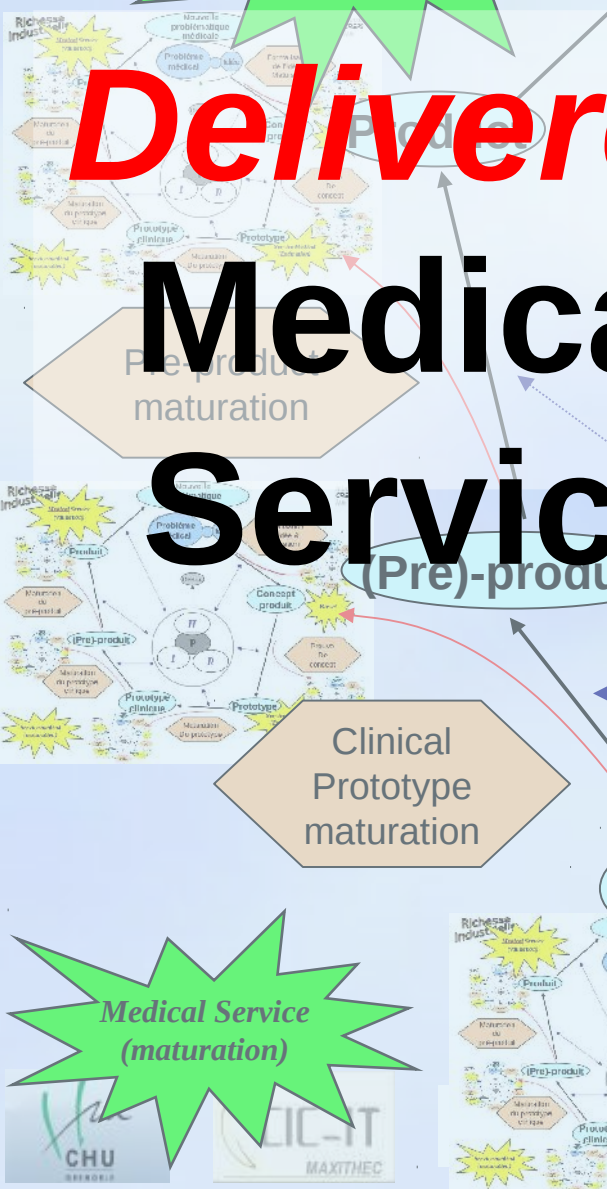
Idea Formalization & Maturation

Delivered

Medical Service

Expected

Medical Service



Medical Service (maturation)

Prototype Maturation

Medical Service (Estimation)

# Three examples of Medical Services of Innovative Medical devices from the CAMI field

## **HEMOCARD**

- *Research project (CHU Grenoble)*

## **Light Endoscope holder Robot (LER)**

- *VICKY® (Endocontrol)*

## **GPS tool for CT-Assisted Interventional Radiological Procedures**

- *IMACTIS GPS system (IMACTIS)*



# HEMOCARD



# HEMOCARD

✦ **An innovative approach to control bleeding with vacuum device**

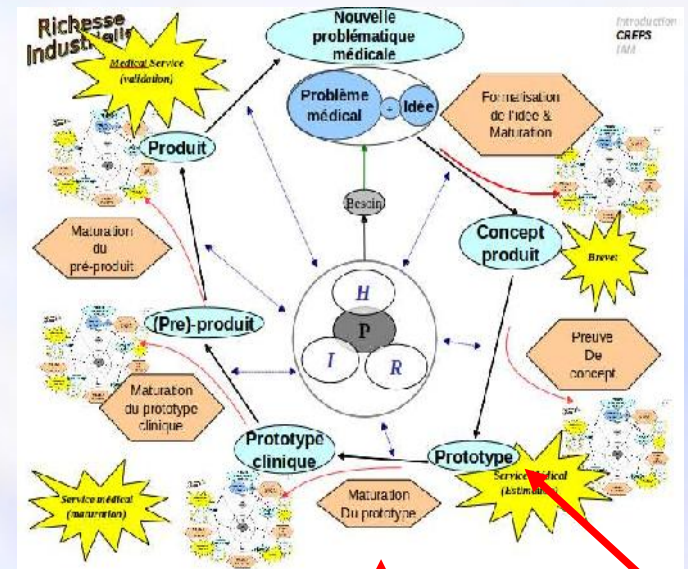
✦ Innovative Medical Device

✦ Class III

✦ Not CE marked

✦ **Expected** Medical Service (2008)

- To control bleeding
  - rapidly
  - In a safer way
  - In stressless conditions
- Bench experiments
- Animal experiments





# HEMOCARD

✦ **An innovative approach to control bleeding with vacuum device**

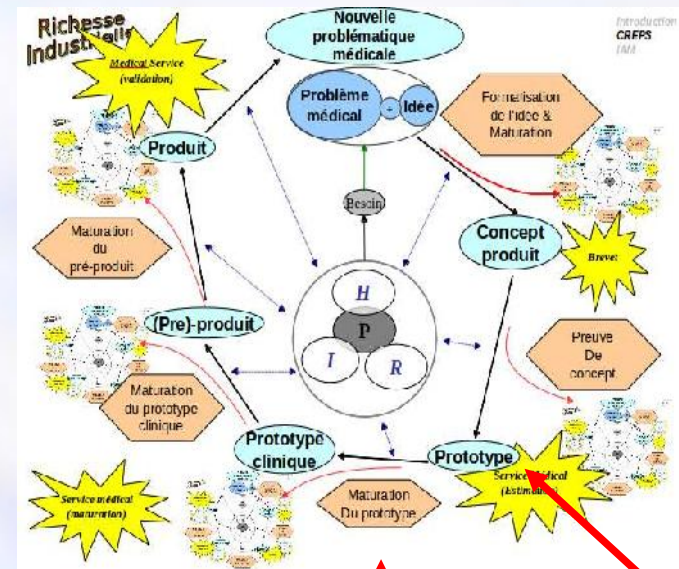
✦ Innovative Medical Device

✦ Class III

✦ Not CE marked

✦ **Expected Medical Service**

- To control bleeding
  - rapidly
  - In a safer way
  - In stressless conditions
- Bench experiments
- Animal (sheep) experiments



**Estimate the Expected Medical Service**  
**An active wound → a dry wound**







# Light Endoscope holder Robot (ViCKY ®)

## Background

2000 : New concept of Light Endoscopic holder Robot

2001-2004 : Maturation of the Expected Medical Service

2005 : Start-Up Endocontrol created

2007 : CE Mark

2008 : FDA approved



# What medical service?

## - To come back to the initial idea

- Robot = mechanical hand
- Robust, but not smart

## - Complications

- Per-operative, post-operative, long-term complication
- Operating duration, length of hospitalization
- Improvement of the visual comfort ?
- Device reliability?
- Learning curve?
- Preferential surgical indication?
- Others ?

# Materials and Method

## Biomedical Research

Equivalence trial

« In term of number of “Hands”, the robot may be considerer as a mechanical hand « equivalent » to those of the operator who holds the laparoscope? »

Multicentric (Grenoble, Lyon, St Etienne)

Prospective

Comparative (Conventional vs Robot)

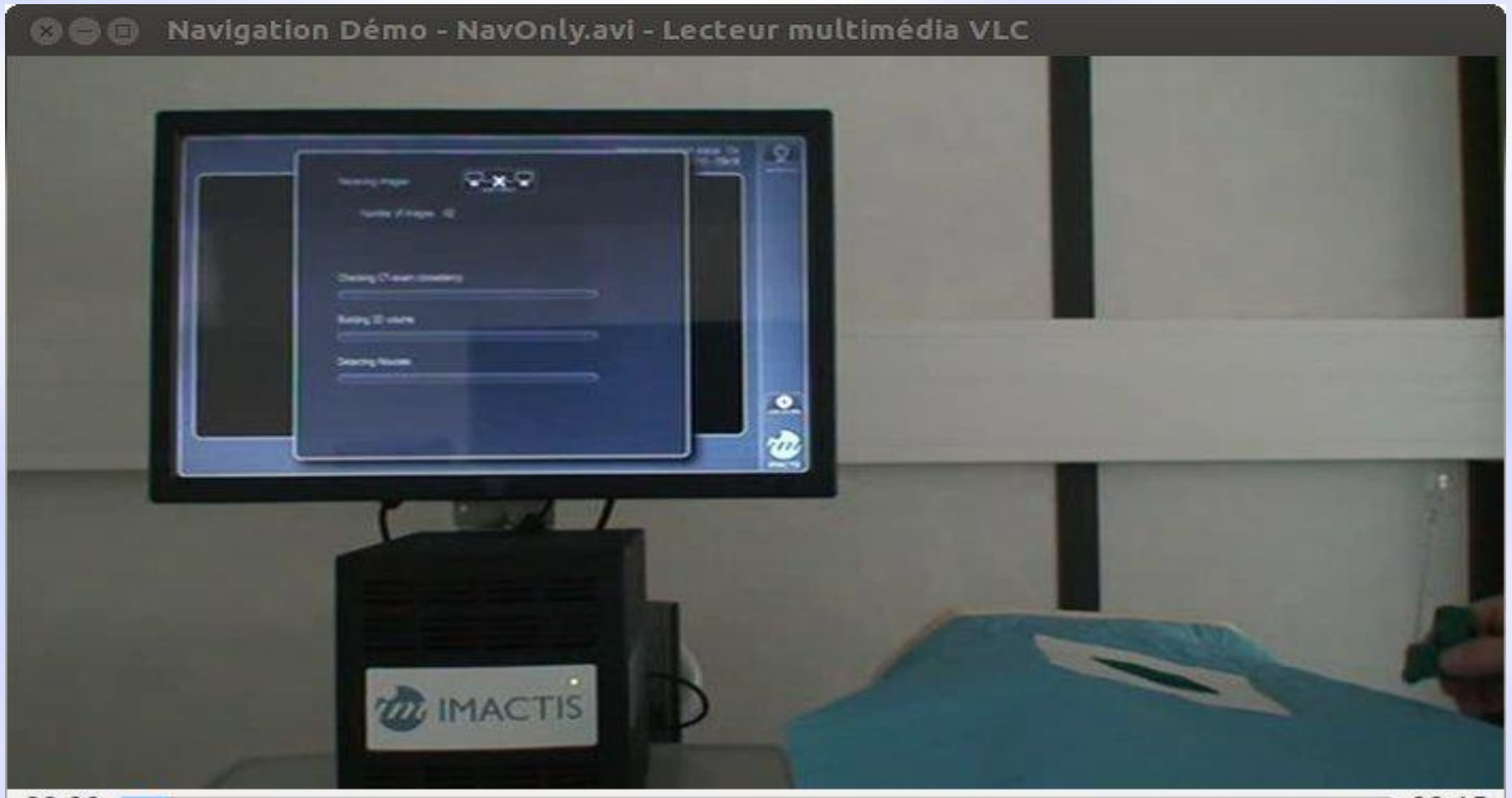
Randomized

Open-label trial

**=> Results to be published**



# An Electromagnetic-localizer navigation system for CT-Based Radiological Interventions





# CT Nav : step 1

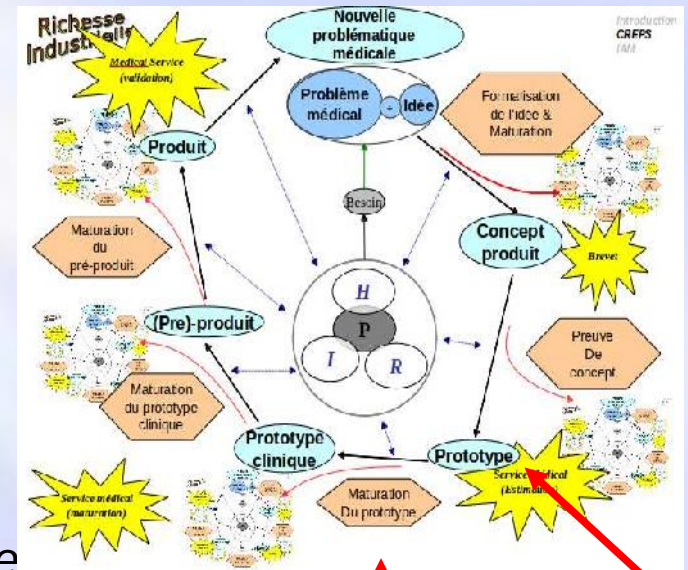
## → *Expected medical service*

✚ A prototype for needle navigation :

- 1/ Position and orientation of the sterile needle holder are displayed in real-time on 2D reconstructed CT-images extracted from the 3D CT volume
- 2 / The radiologist can explore the anatomy of the patient in any plane
- 3/ The radiologist can visualize in real-time the needle trajectory in this plane

### Background

- *Prototype developed during SurgiMaG*
- *Ex vivo evaluations*
  - *Risk Analysis + Bench results*
- ***Expected Medical Service***
  - *To be more precise than Conventional Procedure*



# CTNav : step 2

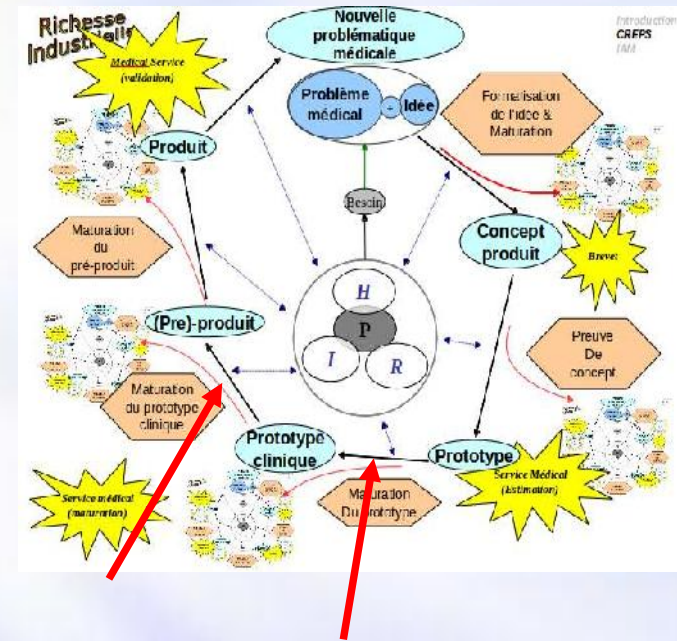
## → First estimation of the delivered medical service

Innovative Medical Device

✦ Class IIa

✦ Not CE marked

- Biomedical research protocol
- Risk Analysis, CPP, AFSSaPS





# CTNav : step 2

## → *First estimation of the delivered medical service*

### Innovative Medical Device

- Class IIa
- Not CE marked

### \*Materials & Methods

- **IRB approved, open, comparative, prospective, randomized controlled trial** (ClinicalTrials.gov NCT00828893).
- N=120 patients randomized
  - standard procedure (CT group) or navigated procedure (NAV group)
  - stratified according to predictable difficulty before intervention
- Main outcome
  - **accuracy** of the needle initial placement, defined as
    - **the maximal *distance*** between planned and realized trajectory
    - **The maximal *angle*** between planned and realized trajectory
- Worse case scenario intention-to-treat (ITT) and per protocol (PP) data analysis.

# CTNav : step 2

→ *First estimation of the delivered medical service*

	CT	NAV	p
population	n=60	n=60	-
distance(mm)	8.9 [4.9; 15.1]	4.1 [2.7; 9.1]	<0.001
angle(°)	7.9 [5.9; 13.2]	4.7 [2.4; 8.2]	<0.001



# CTNav : step 3

→ *to refine the delivered medical service*

## Towards a multicenter clinical trial

→ *national PHRC*

→ *Materials & Methods*

- IRB approved, open, comparative,
- prospective, randomized controlled trial
  - CT vs Conventional
- Main criteria (combined criteria) :
  - SECURITY

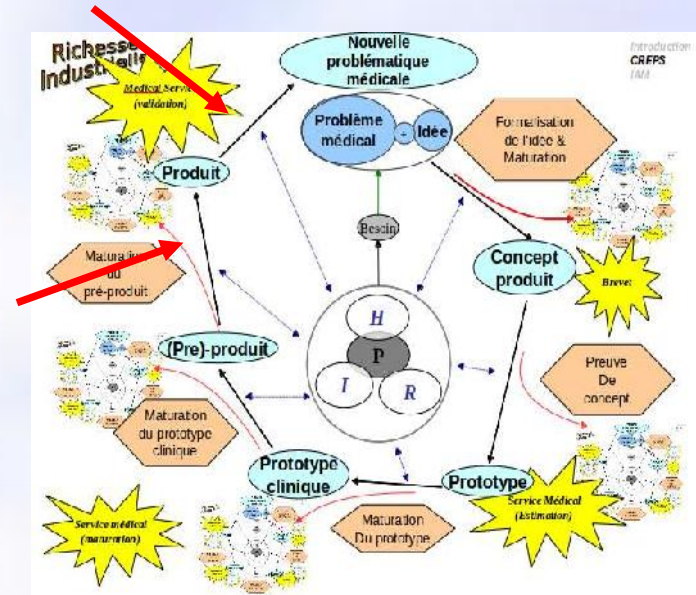
Number of complication directly linked to the puncture gesture

- EFFICICENCY

Number of touched target

- PERFORMANCE

Number of CT-scan performed to put in place the needle



# Challenges

To evaluate:

- as soon as possible
- following an high quality methodology

To facilitate the transfer: **Laboratory** → **Clinical Practice**

To guide the maturation process in the best possible manner

- Of the medical **device**
  - ↙ The time to market
- Of the medical **service**
- ↙ the time to “delivered medical service”





# What are tools are our disposal?

To use according to the degree of maturity of the Medical Device

- ◆ Expected Medical Service

- ◆ In Silico Experiment (Expected medical service)
- ◆ Ex Vivo Experiment (Expected Medical Service)
- ◆ In Vivo Experiment (animals – Expected Medical Service)

Risk Analysis (CE? FDA?)

- ◆ Delivered Medical Service

- ◆ Biomedical research
- ◆ “soins courant”
- ◆ “Observationnelle”



# Are we totally satisfied?

- *Clinical Evaluation*
- **In current practice :**
  - Complex
  - Difficult to implement, especially in the surgical field,
  - With a consistent supply,
  - With a significant cost,
  - To be achieved over a suitable time window of the maturing process of the IT,
  - With a “small” number of patients (around hundred)
  - Etc...
  - **« There is a dearth of such studies ».**



# Are we totally satisfied?

- *Biomedical research* : **YES, NECESSARY!!**

- **BUT NOT ONLY :**

- **REGISTRIES**

- To “capitalize” on the surgeries performed by the Medical Device
  - To access to “Big Data” on medical devices,
  - To share these data,
  - To refine the Medical Service,
  - To better “design” clinical studies,
  - To facilitate Research Program,
  - To facilitate “Post market” follow-up
  - To better structure the knowledge field related to an application

- ...



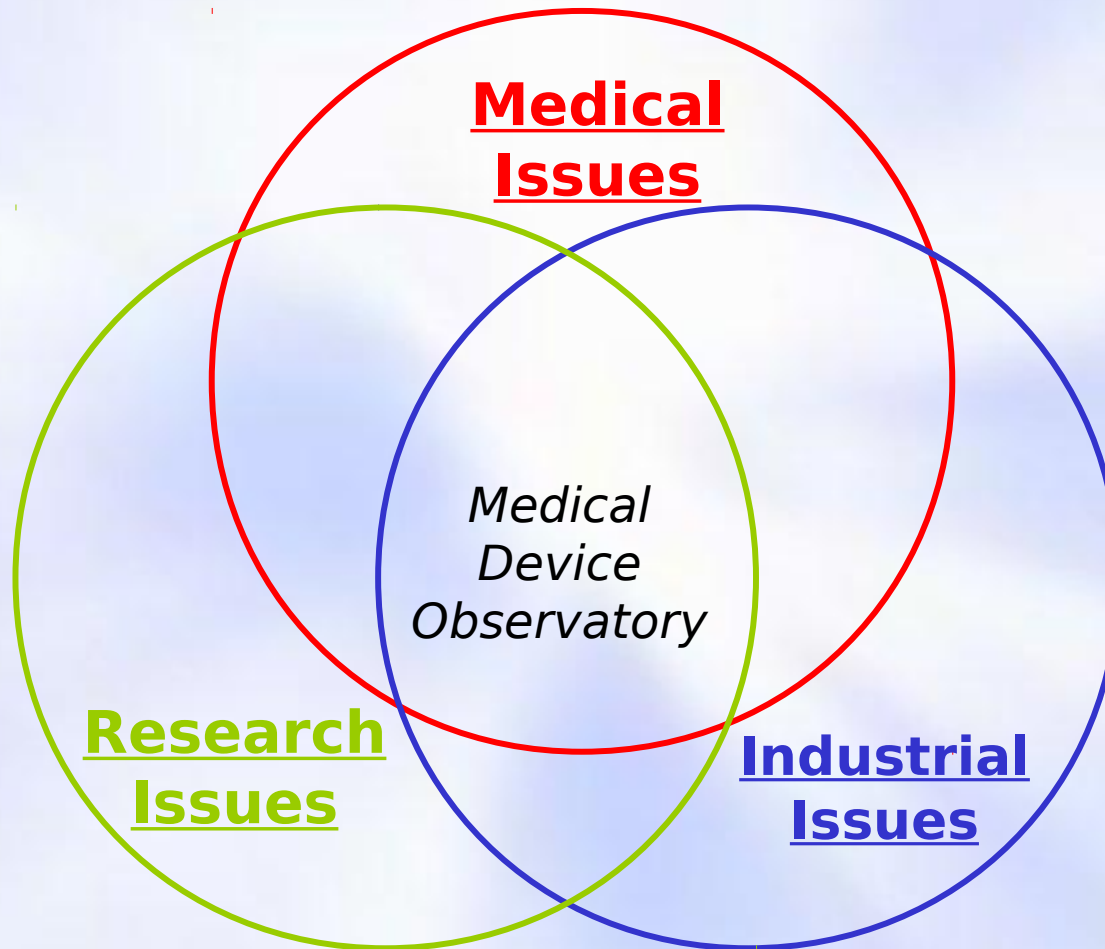
# A CAMI Observatory

Access to objective data about medical practice.

About the impact of new technology

Access to a tool to facilitate the regulatory compatibility (post market surveillance)

Access to high volume data and to realistic models





# Conclusion

To understand the maturation cycle of IT in Health may have advantages:

- to anticipate the next step
- to shorten the maturation cycle
- to ***guide the maturation of the medical service***

To demonstrate the medical service

- Through « Biomedical Research » Tool,
- Through « CAMI observatory » tool

