

Technologie de la santé, de l'innovation au marché  
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# Medical Device Assessment: a regional structure to support Companies

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Hôpitaux de Lyon



# Background 1990 – 2010

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- Observations and expectations
  - Decision makers
    - DRG's
    - COMEDIMS Hospices Civils de Lyon (2000)
  - French National Authority for Health = Haute Autorité de Santé
    - Expected benefit (impact on public health, impact of the product)
    - Improvement of the expected benefit
- Lack of data about medical device effectiveness assessment
- **Objective: Gather all the actors to achieve a same goal**

# Pilot Structure

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- Several sources of funding for each step
  - Conseil Régional Rhône-Alpes + Direction Régionale du Ministère de l'Industrie + Hospices Civils de Lyon
    - Identifying the needs
    - Training of Companies
    - Writing clinical trial protocols (co-financed)
  - MD Companies
    - Conducting the clinical trials
    - Elaborating the reports
- Collaborations: ARDI Rhône-Alpes Santé + OSEO
- Contribution of the French National Authority for Health (events and steering committee meetings)

# First step

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December 2006: Identification of Companies manufacturing medical devices in the Rhône-Alpes Region

- Methods

- Membership of ARTEB association in 2006
- Mailing (postal and electronic)

- Questionnaire survey

- About the needs and expectations of Companies relative to medical devices assessment

# Results of the survey (1)

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- 40 participants
  - 85% Small Business
  
- Destination of the medical device
  - 90% for hospital use
  - 53% with reimbursement strategy
  
- Studies performed for marketing
  - Technical studies: 95%
  - Interventional or comparative clinical trials: 53%
  - Registries: 28%
  - Health Economic studies: 25%

*(Total > 100% due to multiple choice)*

# Results of the survey (2)

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- 28% respondents had a dedicated internal structure dedicated to medical device assessment
- A specific need was expressed for:
  - Methodological support and trial protocol writing: 88%
  - Conduct of trials: 90%
- Free comments and specific needs concerning:
  - Methodological and logistical information to conduct clinical trials
  - Clarifications about the requirements of HAS for MD reimbursement process

# Second step

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24 & 25 January 2007: Information and training session

- Participants

- 31 Companies, 40 persons

- Contributors

- University, Hospitals, Lawyers, Health authorities
- Methodological aspects of clinical and health economic assessment of MD, regulatory aspects
- Discussion with Health authorities

⇒ **17 applications for pilot structure support**

# Third step

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6 March 2007: Selection of the projects

- Preliminary individual meeting with a team of methodologists
  - Instruction and orientation
  
- Selection based on the formal interview of the 17 project managers by the Steering Committee
  
- Selection criteria:
  - Scientific = innovation
  - Financial = eligibility to award a grant
  - Feasibility and methodological aspects

# Results of the selection

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- 13/17 projects selected for support
  - Selected: 7 for immediate support and 6 with support delayed in time
  - Not selected:
    - 1 project definitely rejected
    - 3 projects needing complementary instruction (redirection)
- Steering Committee meeting on 26 September 2007:
  - New audition for 2 projects redirected → selected
  - 3 new innovative projects examined → selected
  - Among selected projects: 1 withdrawal (strategic choice)

⇒ **17 projects supported by the pilot structure**

# Fourth step

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From March 2007: Protocol writing

- Written protocols ready for submission to competent authorities for research authorization
  - **9 protocols (53%)**
  - Median time for writing a protocol = 13 months (min = 6 months ; max = 25 months)
  
- Non written protocols
  - 7 due to strategic choice by the industrial
  - 1 medical device still under development

# Fifth step

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## Conducting of the trials

- Clinical trials
  - **2 trials ongoing**
  - 2 trials to be implemented
    - Regulatory proceedings for 1 trial
    - 1 protocol still under writing, scheduling to start the study in June 2011
  - 1 trial conducted out of the structure
  
- Studies not implemented
  - 3 due to strategic choice of the company (financial issues)
  - 1 due to withdrawal of the clinical investigator

# Synthesis

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- Difficulties highlighted
  - Methodological issues linked to the medical device
  - Financial issues for the conducting of a clinical trial
  - Problems for initiating the trial, including identification of an investigator
  
- Anticipating the duration of the different steps
  - Writing a protocol
  - Regulatory process
  - ...

# Recommendations

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## Needs for MD Companies

- Engineering files
  - Assessment culture
  - Trained people
- Knowledge of clinical environment
  - Local / Regional / National / International

### ⇒ Supportive structures

- Based on Regional network and scientific committees
- With interconnection at the national level

***Thank you for your attention !***