

# Programa Cooperación Farma-Biotech

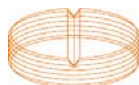
Jornada IV: Ámbitos terapéuticos relacionados con respiratorio,  
dermatología, nefrología, inflamación e infección

## ***SNF 472, a new approach to cardiovascular calcification in renal disease***



**SANIFIT**  
LABORATORIS

Madrid, 12 July 2011



## Content

### 1. The Company

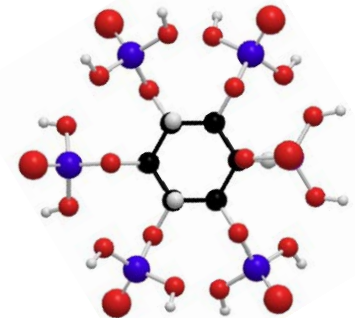
### 2. The Product

- a) Therapeutic focus
- b) Innovative mechanisms of action
- c) Differential features facing the market
- d) Current status of development
- e) IPR protection
- f) Pitfalls & Risks to be considered

### 3. Availability for cooperation

# Sanifit - the company

- ✧ **New approach to treat calcification diseases and related health problems**
- ✧ **Drug pipeline: cardiovascular/ nephrology/ urology**
- ✧ **Medical nutrition/medtech /OTC pipeline**
- ✧ **1st dental product licensed; launch Q2/12,**
- ✧ **International management team**
- ✧ **Shareholders: VC, mgmt, private investors**
- ✧ **Business model: licensing / partnering for IP after proof of concept**



# Sanifit – Therapeutic focus

**Solid Ca**

**Soluble Ca**

**Solid Ca**



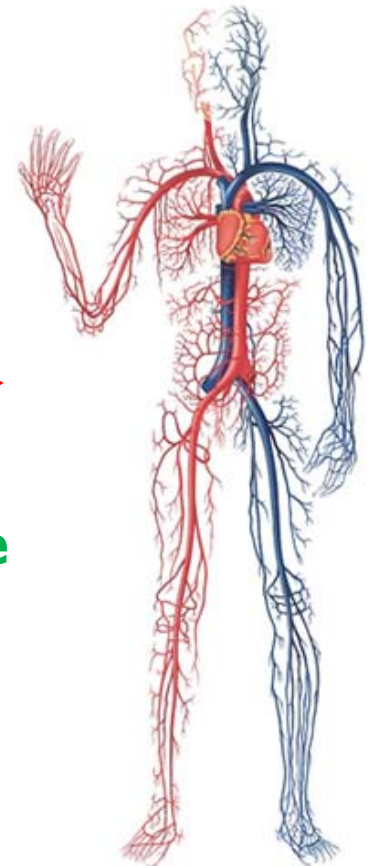
**Bone**

**Inhibit**  
→  
**Enhance**  
←



**Blood**

**Inhibit**  
→  
**Enhance**  
←



**Soft tissue**

# Sanifit – Therapeutic pipeline

*Cardiovascular/ Nephrology:*  
Cardiovascular disease in ESRD  
patients under dialysis  
0.5-1M patients USA+EU

*Urology:*  
Recurrent kidney stones due to  
hypercalciuria  
1-2% of population

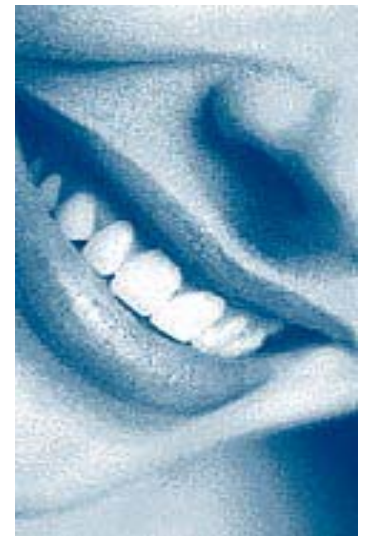


# Sanifit – other pipeline activities

*Nutritional care: osteoporosis/*

*Medical devices/ surgical implants*

*Dental- OTC/ anti-tartar*



# Pipeline status



ASB 01 Dental

SNF 472 Nephrology / CV

SNF 571 Kidney stones

Medical nutrition

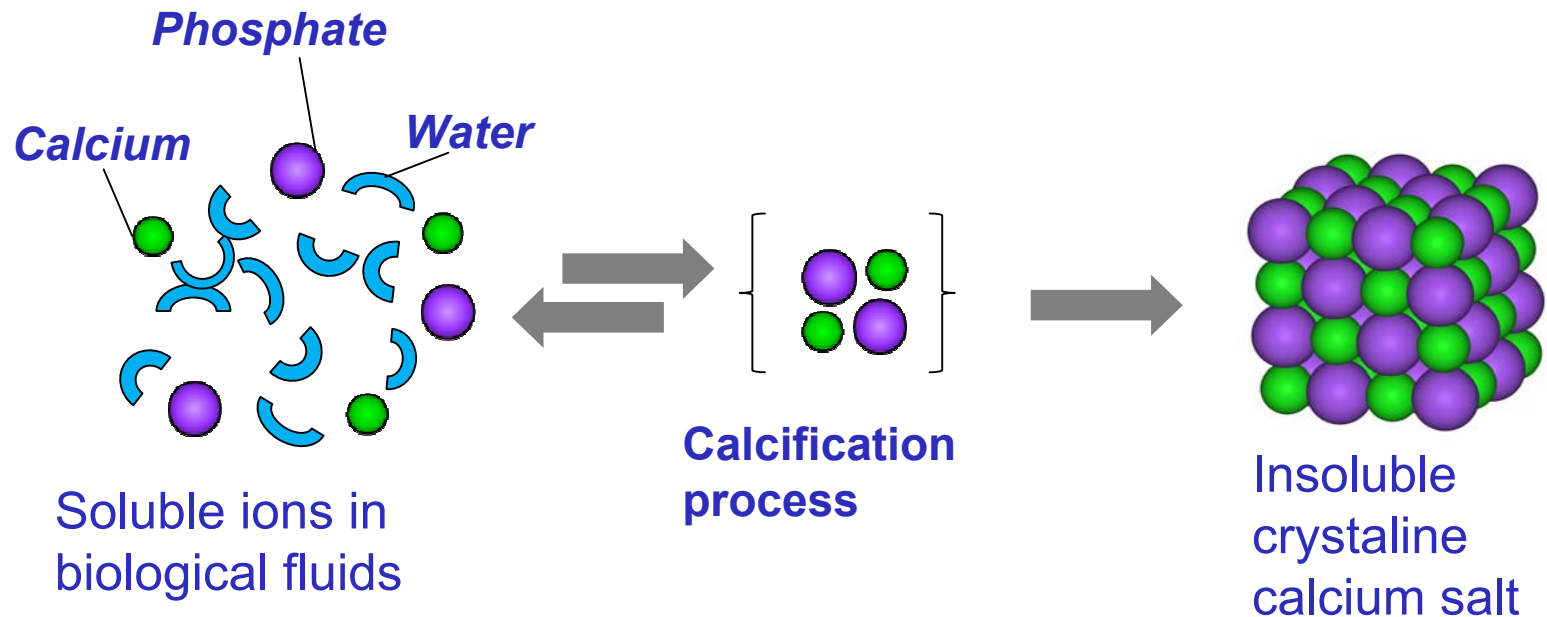
Medtech

NDL

*New drug leads*

# IP6: a unique mode of action

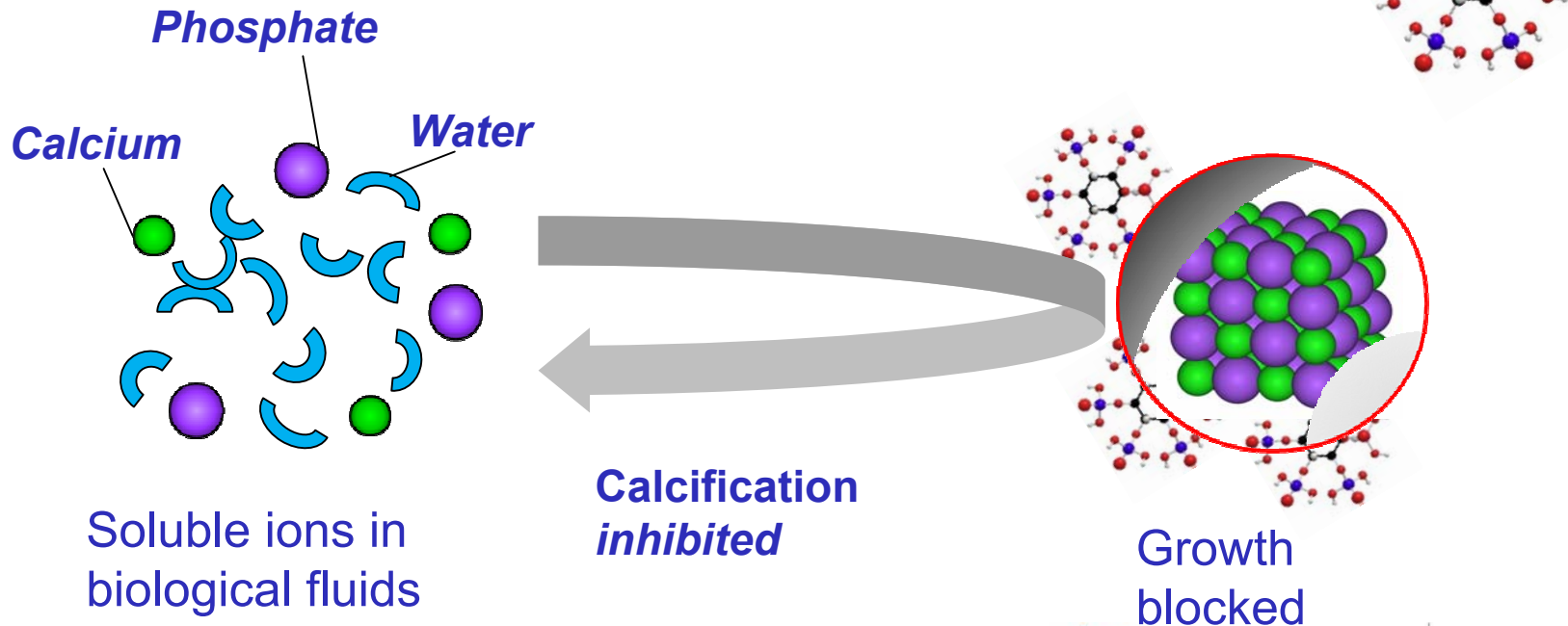
\* **Biological calcification is a crystalization process**





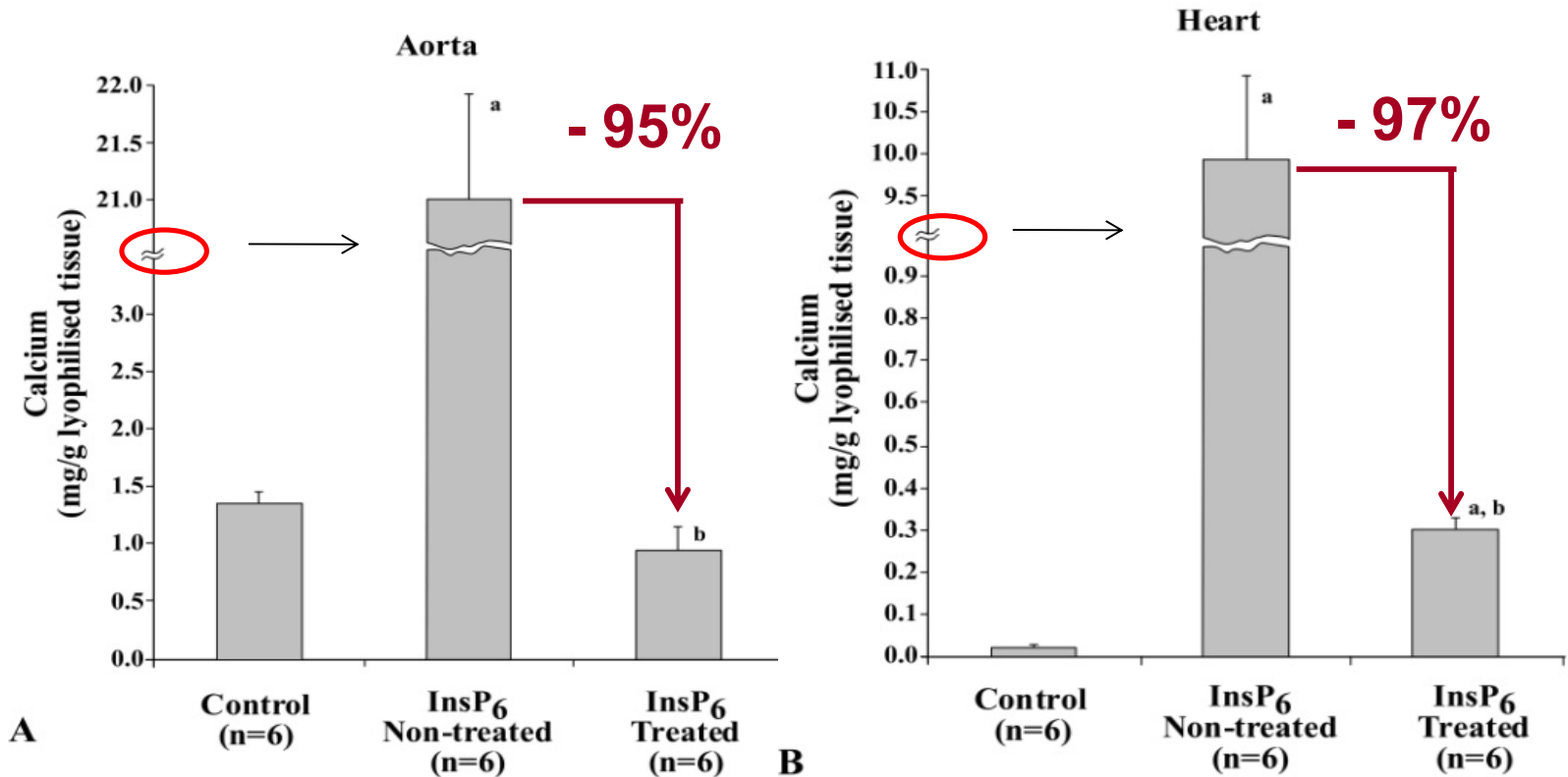
# IP6: a unique mode of action

- \* IP6 blocks crystal growth / No interaction with free calcium
- \* Most potent inhibitor known, submicromolar levels *in vivo*



# IP6: Highly effective in animal models

## Rodent model (vit. D -induced calcification )



# SNF 472 development status

- \* **Oral availability severely limited**
- \* **New range of formulations matching indications**
- \* **Full GLP & GMP pharmaceutical development i.v. / topical /oral**
- \* **Development from natural product to NCE completed for i.v.**

**Intravenous**



**Transdermal**



**Dental**



**Nutrition**



# SNF 472 development status

- **Preclinical efficacy studies in animal models**
  - SNF 472 is effective in blocking calcification in animal models
- **GLP preclinical safety, toxicology & ADME studies**
  - SNF 472 is safe through i.v injection with a wide (500-1000x) therapeutic window (single / 28 day multiple)
  - Long term tox studies underway

# Product . Differential features

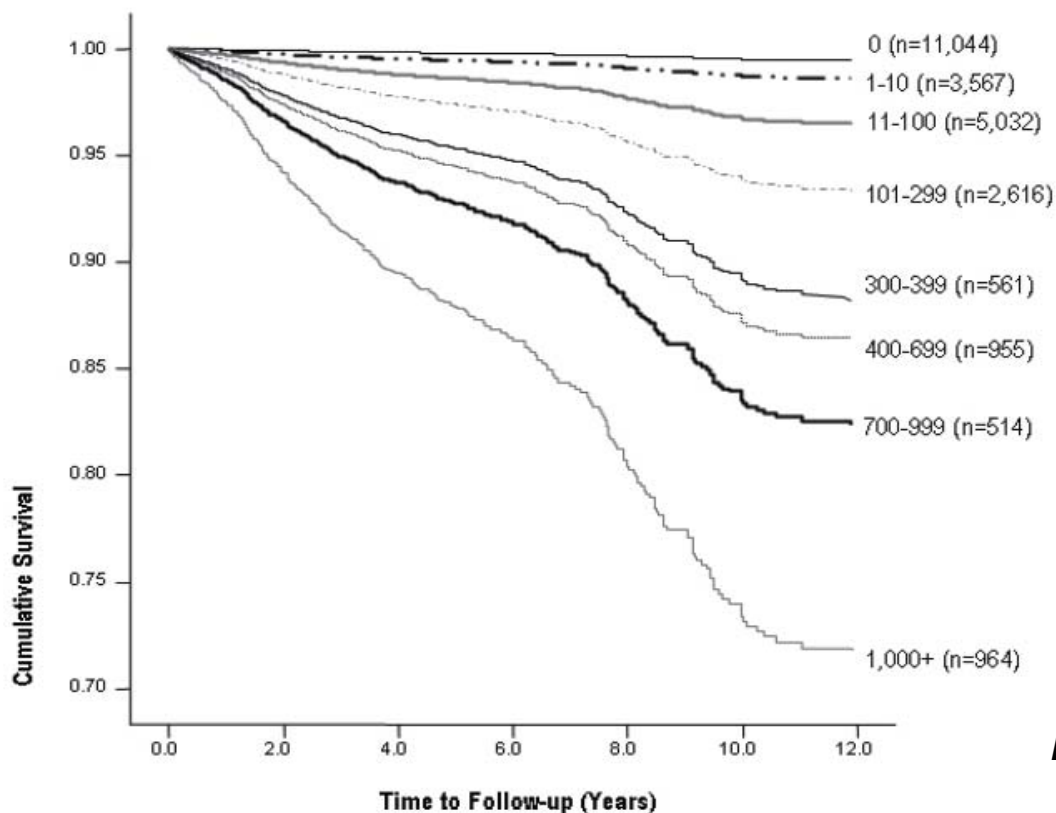
SNF 472 for End Stage Renal Disease  
patients under dialysis



**Kidney / heart  
disease**

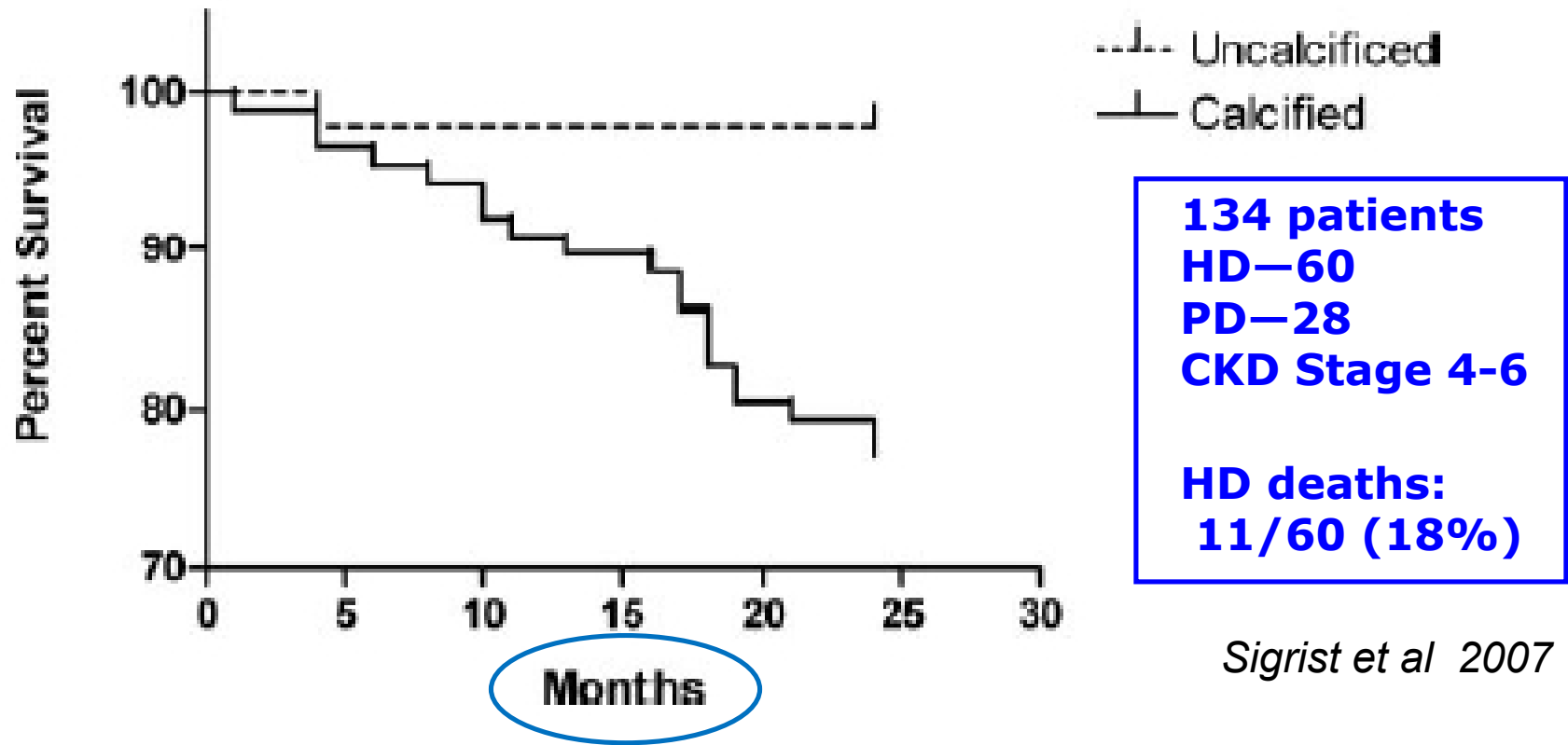
# Cardiovascular calcification: unmet need

## Cumulative Survival by Coronary Calcium Score



*Budoff and Gul 2008*

# Faster CV calcification & higher mortality in hemodialysis patients

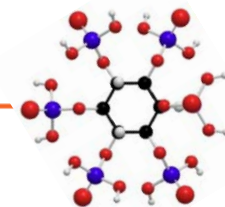


# Clinical strategy rationale

- **Cardiovascular events due to calcification: main cause of death in ESRD patients under dialysis**
- **Current treatment:**
  - reduction of Calcium (via control of PTH pathway)
  - reduction of Phosphate blood levels (via control of phosphate intake)
- **Sanifit's SNF 472 blocks calcification, with action independent of Ca / Phosphate levels**



# Product profile (*draft*)



- ✧ New treatment option for reduction of cardiovascular events in ESRD patients under dialysis
- ✧ I.V. injection every other day (per dialysis session)/ good compliance
- ✧ Active independently of calcium and phosphate levels
- ✧ Sub-micromolar potency -plasma calcium levels intact
- ✧ Excellent (preclinical) efficacy and safety profile
- ✧ No serious drug interactions / combination therapy option
- ✧ Low COGs / stable r.t.

# Intellectual Property

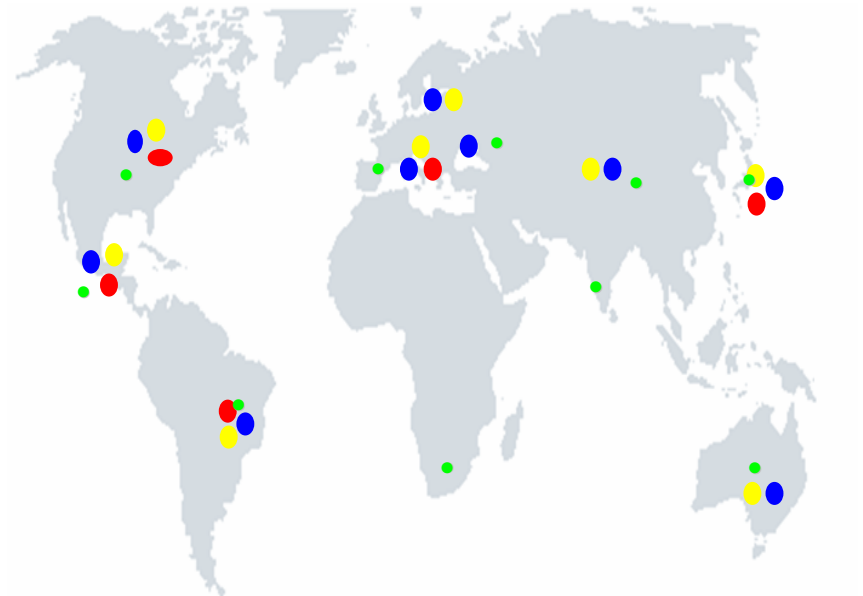
**Strong patent coverage of medical use and critical delivery routes for the main diseases in all major markets**

**Cardiovascular & Renal Lithiasis  
(topical administration)**

**Dental applications/Oral hygiene**

**Osteoporosis**

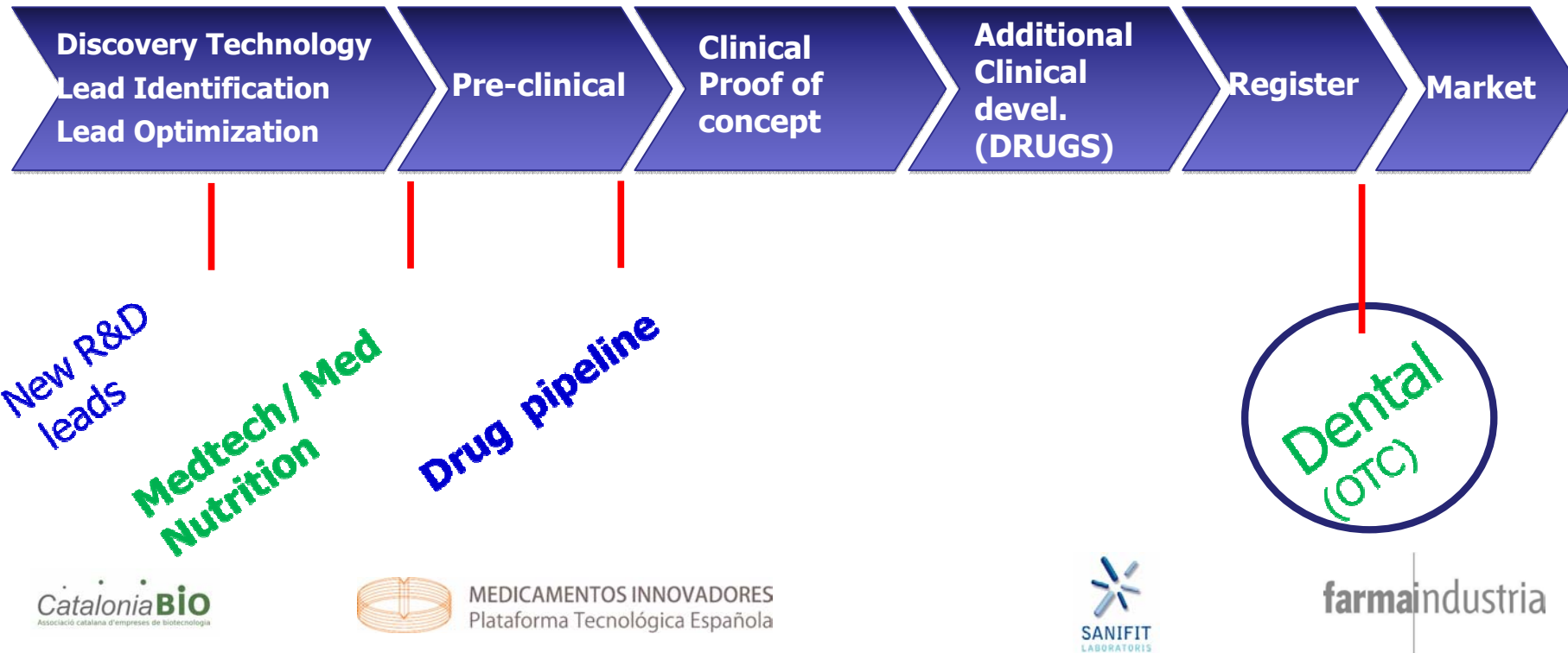
**New Patent Applications**



# Business Model

- \* Business model built on cooperation
- 1. Product development until PoC

## \* Sanifit



# Business Model

1. Product development until PoC
2. Out-licensing / partnering

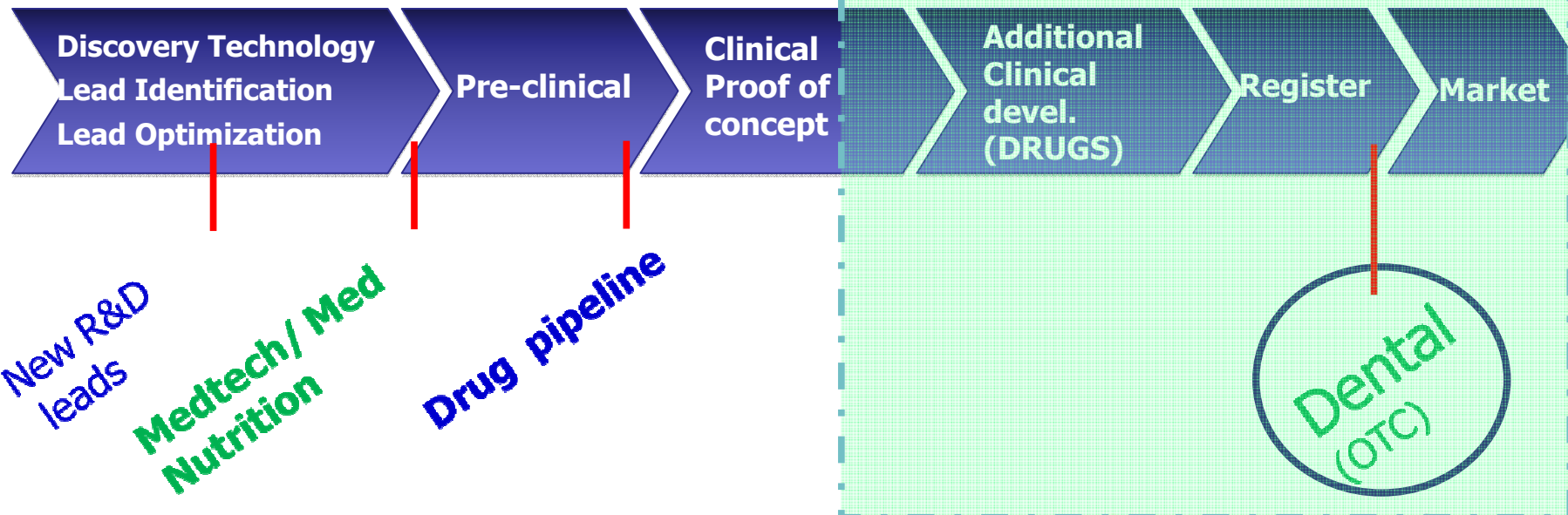
**Royalties**

**Milestones**

**Signing fees / co-development**

\* **Sanifit**

**Partners**



# Thank you.

**Special thanks to  
Farindustria and all the  
participants**

*Contacts for more information*

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## SANIFIT

**New approach to  
calcification disorders**

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