Oportunidades de Financiamento e de Cooperação em I&D e Inovação em Saúde

Sanofi

Carlos Santos
2.10.2014

SANOFI

OUR GROUP

We are a **global healthcare company** engaged in the research, development, manufacturing and marketing of healthcare solutions.

€33 bn*
In sales in 2013

** €32,951 M*

R&D
A major biopharmacy player

- **45%** of revenues generated by biologics
- **80%** of development projects are biologics

present in more than **100** countries

112
Industrial sites in 41 countries

more than **110 000** employees

A comprehensive offering
of pharmaceuticals, vaccines and innovative therapeutic solutions

Information of December 31st 2013

SANOFI

R&D Pipeline Summary Table[1]

	Phase I	Phase II	Phase III	Registration	TOTAL
Oncology	6	3	0	0	9
Diabetes Solutions	1	0	1	1	3
Cardiovascular / Renal Diseases	0	1	1	0	2
Immune Mediated Diseases	2	3	1	0	6
Infectious Diseases	0	2	0	0	2
Ophthalmology	3	0	0	0	3
Rare Diseases	3	1	1	1	6
Age Related Degenerative Diseases	1	1	0	0	2
Vaccines	2	4	4	2	12
TOTAL	19[2]	15	8	4	

34[2]

34

12

46

NMEs & Vaccines

(1) Excluding life cycle management programs
(2) Includes 1 Phase I project addressing an undisclosed target

Study Type

- Clinical Study
  - Phase I
  - Phase II
  - Phase III
  - Phase IV
- Bioequivalence Study
- Pre-clinical Study
  - In vitro
  - In vivo
  - Ex vivo
- Prospective Product Registry
- Retrospective Product Registry
- Disease Registry

Sponsor

- Company Sponsored trial

- Investigator Sponsored Trial (IST)

- Investigator Sponsored Studies (ISS)

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Study Outline Template

Study outline template for local/regional Medical Affairs studies

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WARNING: for pre-clinical studies, only information highlighted in red is mandatory

Part 1: Study Information

Date of Study Outline submission (dd/mm/yyyy)

Submitted by (name): Lead Country:

Product Name®: INN:

Managing Medical Unit:

☐ Corporate ☐ Region, Specify ☐ Affiliate, Specify

Study Title:

Study Number: Short Title:

Main Strategic Objective:

- ☐ Benefit/Risk management
- ☐ Regulatory requirements
- ☐ Support pricing and reimbursement
- ☐ Launch related support
- ☐ Differentiation versus other Product
- ☐ Support of third party research

Specify* _____

- ☐ Medical Affairs Life Cycle Management
- ☐ Other studies, in particular support of a strategic lever

Specify* _____

* Mandatory if the corresponding box is ticked

- ☐ Bioequivalence
- ☐ Pre-clinical study (in vitro, in vivo, Ex vivo)

Please attach full project description in English

Study rationale (Medical):

Brief summary which should include the following points:

- brief description of the medical rationale
- rationale for the dose and schedule outlined for all treatment arms
- reference any non-labeled indication
- communication plan

Sponsor:

- ☐ Company Sponsored Trial (specify company entity's name)
- ☐ Investigator Sponsored Trial (IST) / Investigator Sponsored Studies (ISS) (specify sponsor's name)

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Version Number: 4.0 01-March-2014

Study outline template for local/regional Medical Affairs studies

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Study type:

Group a

- ☐ Clinical study
  - ☐ Clinical Study Phase I
  - ☐ Clinical Study Phase II
  - ☐ Clinical Study Phase III
  - ☐ Clinical Study Phase IV

Group b

- ☐ Compassionate

Group c

- ☐ Prospective Product Registry
- ☐ Retrospective Product Registry

Group d

- ☐ Disease Registry

- ☐ Bioequivalence study
- ☐ Pre-clinical study (in vitro, in vivo, Ex vivo)

Number of centers:

Including selection of centers and representative countries

Principal investigator Name:

Country:

Number of subjects: N=

Sample size

Distribution by country or region

Statistical power and sample size justification

Number of subjects per treatment arm

Participating countries:

Regions involved if countries not known (e.g. EU & USA):

Study duration and dates (from first site (dd/mm/yyyy))

Protocol planned date

First patient in (Start of recruitment)

Last patient in

Last patient Out (End of recruitment)

Estimated recruitment duration

Estimated average treatment duration

Database lock planned date

Estimated Report date

Indication:

Study Objectives (Primary / Most Important Secondary):

Primary: Secondary:

Study Population: Brief description of subjects to be included by addressing the major inclusion and exclusion criteria

☐ Including pediatric patients ☐ Including elderly patients

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Study Outline Template

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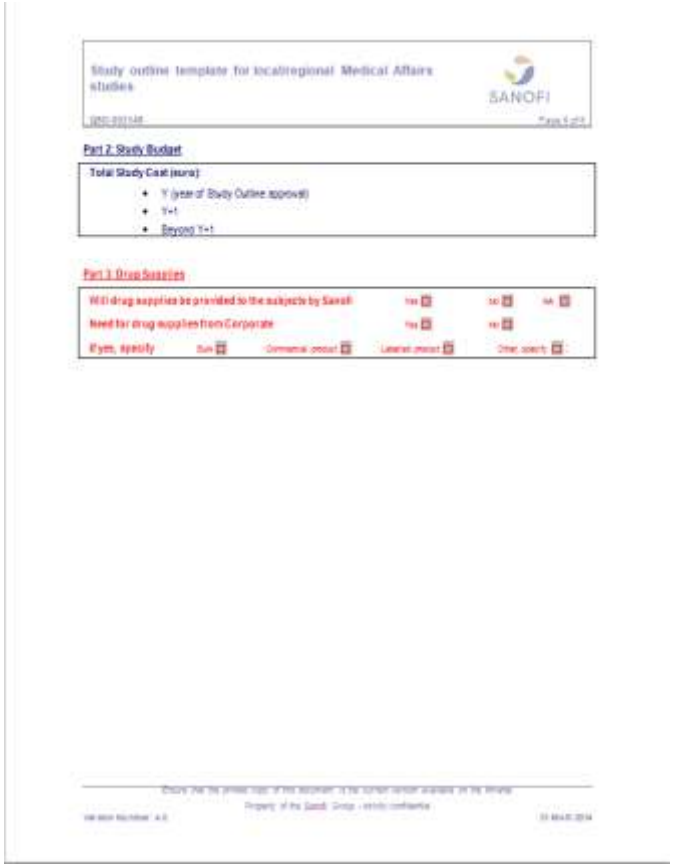
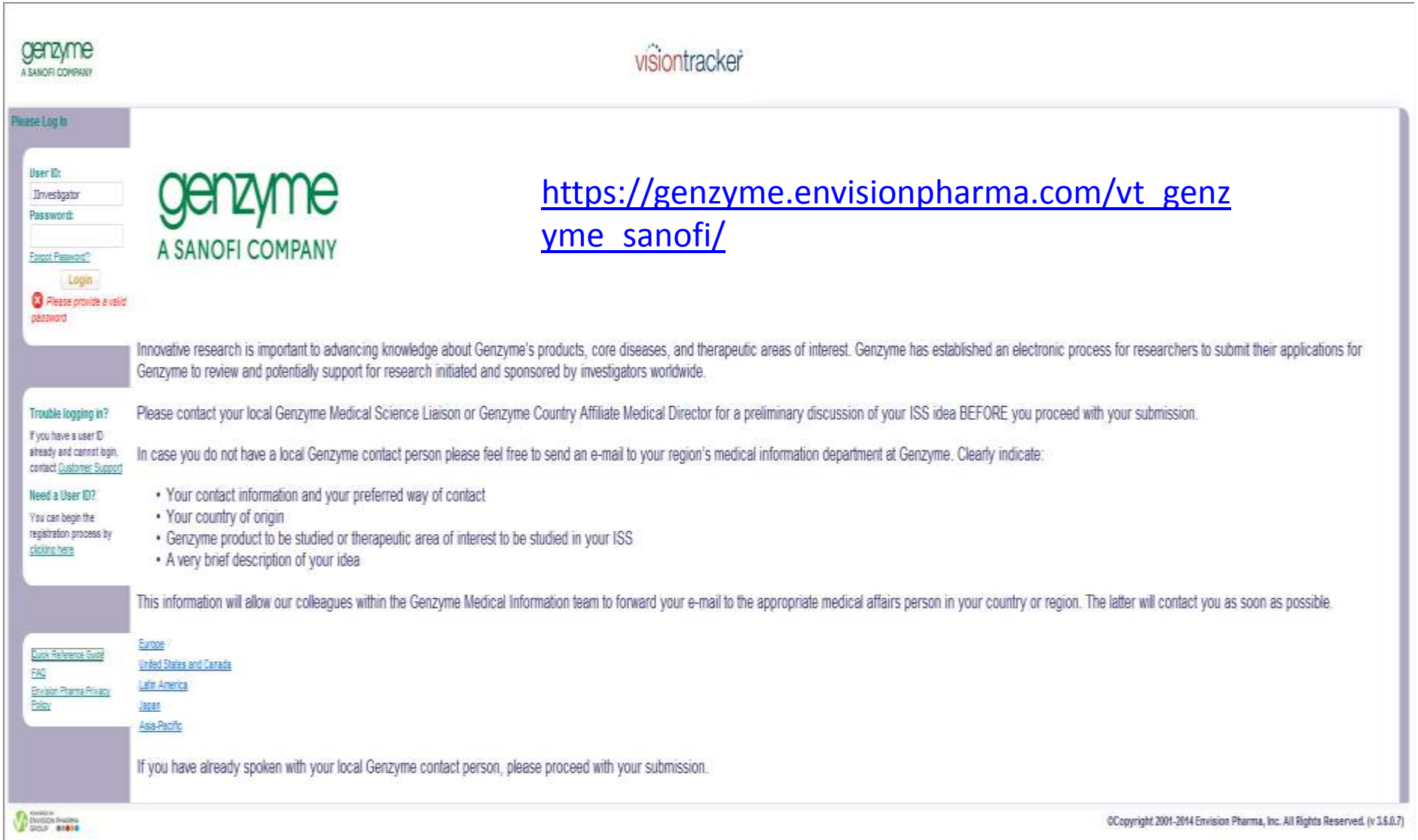
Inclusion Criteria:	Exclusion Criteria:
Study Design: A brief summary of design should consider the following points: • Controlled/non-controlled, type of control • Open/single-blind/double-blind/observer-blind • Randomization (including randomization ratio) • Parallel-group/crossover/strata • Other + Study design scheme when available	
Treatments: Summary including the following points: • Test and comparator treatment products, • Dosage and dosage regimen for all study periods (if applicable), • Duration of treatment, including the number of scheduled visits, • Formulation, presentation/form and strength(s) for both test and comparator products, • Route of administration, • Blinding techniques	
Evaluation Criteria: • Primary endpoints • Secondary endpoints	**Data collected:** • Efficacy • Safety And if applicable: QOL, Health economics, PK/PD
Additional useful information	



visiontracker

Visiontracker
POWERED BY ENVISION PHARMA GROUP



Visiontracker

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visiontracker

Electronic process for researchers to submit their applications for Genzyme to review and potentially support for research initiated and sponsored by investigators worldwide

WHO IS ELIGIBLE

Researchers worldwide may apply to Sanofi/Genzyme for research support involving:

- Clinical studies of a marketed Sanofi/Genzyme product or device, including research of an unapproved new use (disease or indication).
- Observational studies, such as epidemiologic research in any of Sanofi/Genzyme's core diseases or therapeutic areas.
- Health outcomes research, especially related to core therapeutic areas.
- In vitro and animal studies of a marketed Sanofi/Genzyme product or device.

Study Type

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  - Phase IV
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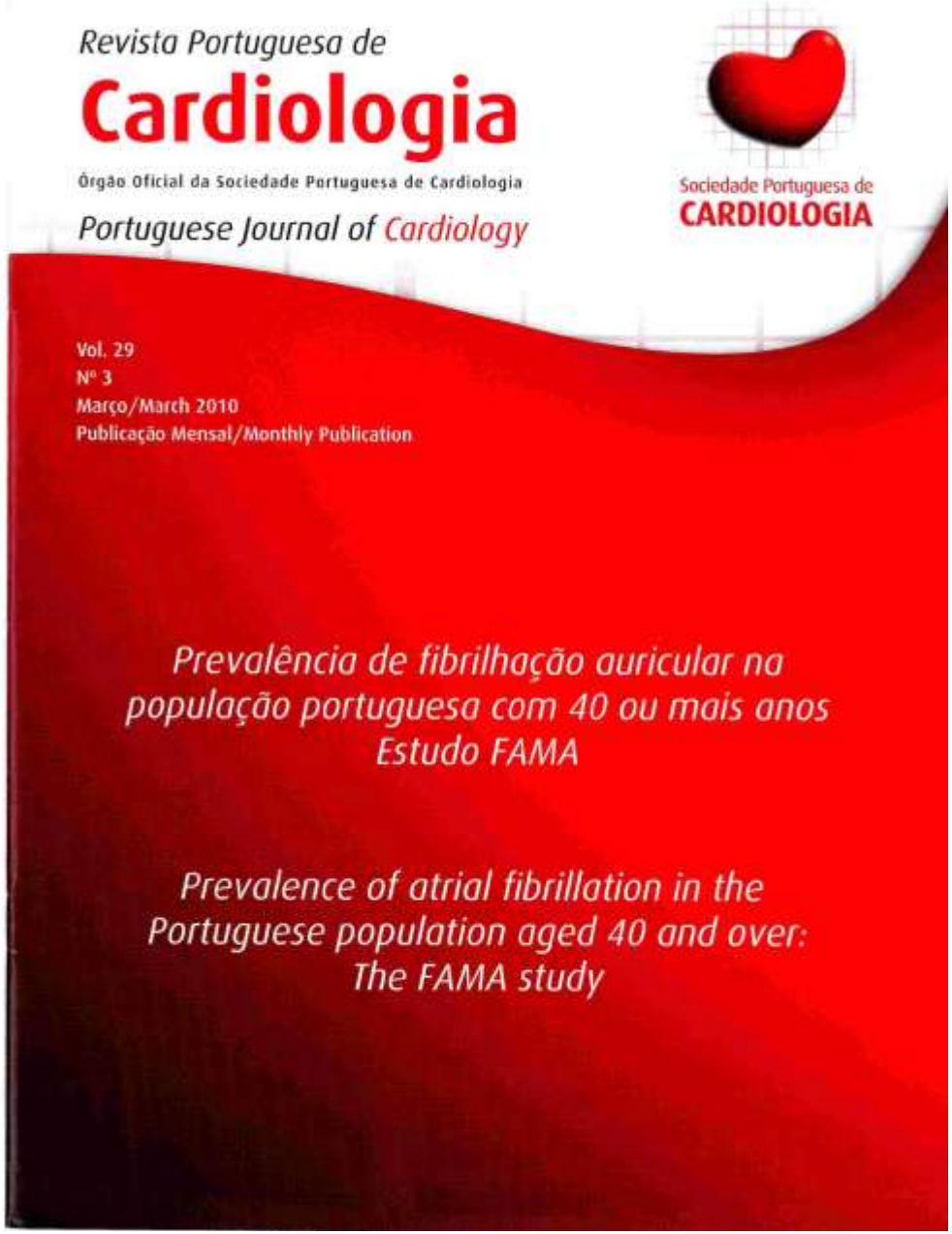
- Pre-clinical Study
  - In vitro
  - In vivo
  - Ex vivo
- Prospective Product Registry
- Retrospective Product Registry
- **Disease Registry**

ATRIAL FIBRILLATION IN PORTUGAL



Prim Care Diabetes. 2014 Aug 14. pii: S1751-9918(14)00075-8. doi: 10.1016/j.pcd.2014.06.004. [Epub ahead of print]

Metabolic control and therapeutic profile of patients with diabetes in Portuguese primary care (TEDDI CP).

Cardoso SM[1], Rodrigues E[2], Valadas C[3], Fonseca C[4]; on behalf of TEDDI CP investigators.

Author information

Abstract

AIM: To evaluate the metabolic control rate and to characterize the therapeutic profile of patients with Type 2 diabetes mellitus (DM2) from Portuguese primary care of National Health Service.

METHODS: Cross-sectional multicentre study conducted in Portuguese primary health care units between July 2011 and May 2012. A national representative sample of 1528 DM2 patients was selected from 51 units, stratified by region. Socio-demographic, anthropometric, lifestyle, cardiometabolic risk factors, disease status, HbA_{1c} levels and therapeutic information were collected.

RESULTS: Patients' mean age was 65±10.7 years (50.4% males) and median duration of disease was 7 years: range (0-45 years). Almost 8% were smokers, 80.3% had hypertension, 61.6% hypercholesterolemia and almost 15% cardiovascular disease. Patients' health condition was classified with a score of 4 or 5 (excellent) for 60.6%. Median HbA_{1c} was 6.6% (min-max: 4.2%-13.4%), 64.8% of the patients had HbA_{1c}<7.0% and 49.2% HbA_{1c}≤6.5%. Oral antidiabetics were used in 94.4% of the patients, antihypertensives in 80.6%, antidyslipidemics in 72.0%, antiplatelet agents in 50.6% and insulin in 8.3%.

CONCLUSIONS: Metabolic control rate was good according to current guidelines. However, patients with higher HbA_{1c} levels had longer time since diagnosis, worse current health condition, hypertriglyceridemia and were insulin-treated.

KEYWORDS: HbA(1c); Prevalence; Primary care; Type 2 diabetes

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Metabo

WCC/ESC Barcelona 2006

SAS Paris 2006

CNMF Aveiro 2006

SPDiabetologia Algarve 2006.

SPC Algarve 2006.

w-risk

BODY WEIGHT DEVIATIONS AND RISK SITUATIONS

Abdominal Obesity is an Additive Marker of Risk for Cardiovascular Disease in Primary Care Patients in Portugal

M. Cardoso[1], E. Meadas[2], V. Gil[2], on behalf of W-RISK investigators [1]Faculty of Medicine, Coimbra, Portugal; [2]PRIMOS, Lisbon, Portugal; [3]Hospital Fernando Fonseca, Amadora, Portugal

ABSTRACT:

PURPOSE:
To analyze the importance of abdominal obesity as a marker of cardiovascular risk in a Family Physician (FP) population aged 18 years or older in Portugal.

BACKGROUND
Abdominal obesity is being recognized worldwide in several clinical and epidemiological studies as an important marker for cardiovascular diseases.

Regional differences regarding prevalence and clinical importance must be adequately addressed.

No reliable data exists about the role of abdominal obesity as a marker of cardiovascular risk in Portugal.

METHODS:
A representative sample of FPs from the Public Health Care centres was identified in Portugal, randomly selected from the most exhaustive list available.

On 3 consecutive days, all patients aged ≥ 18 years consulting their FP (for whatever reason) were invited to participate. Each FP recruited a maximum of 10 patients.

Written informed consent was obtained from each participating subject.

A standardized questionnaire allowed to determine the prevalence of obesity (BMI: kg/m²), abdominal obesity – measured by waist circumference (WC; cm), and associated cardiometabolic risk factors and cardiovascular disease.

Overweight was defined as BMI between ≥ 25 and < 30 kg/m², and obesity as BMI ≥ 30 kg/m².

For abdominal obesity the IDF definition for the WC threshold was used: women > 80 cm; men > 94 cm.

WC was measured midway between the lowest rib and iliac crest using a tape measure.

A descriptive analysis has been used.

Prevalences were age standardized.

RESULTS:
Data were collected from 14,686 subjects consulting their Family Physician (1,580 FPs).

Mean age of participants was 55.5 ± 16.2 years; 65.9% were female.

Prevalences of overweight, obesity and abdominal obesity were respectively 44.9%, 27.2% and 46.3% in men, and 35.9%, 34.6% and 62.9% in women.

The standardized prevalence of hypertension, diabetes and hypercholesterolemia were respectively: 33.1%, 9.2% and 37.0%.

Fig. 1: Distribution of weight by BMI in men, women and in the total group (% of patients).

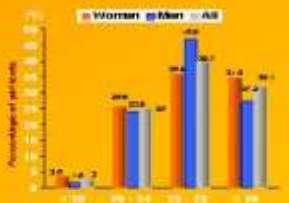


Fig. 2: Distribution of abdominal obesity by age group in men and women.

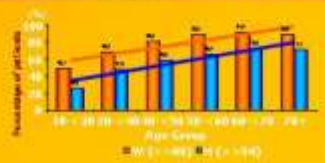


Table 1: Risk of cardiovascular disease associated with major risk factors and abdominal obesity in the overall population (adjusted for age).

RISK FACTOR	OR for CVD
HYPERTENSION	2.5 (2.1 – 3.0)
DIABETES	1.6 (1.4 – 1.9)
HYPERCHOLESTEROLEMIA	1.6 (1.3 – 1.8)
HYPERTENSION + AO	3.8 (2.8 – 5.1)
DIABETES + AO	2.4 (1.9 – 3.0)
HYPERCHOLESTEROLEMIA + AO	1.9 (1.5 – 2.5)

CONCLUSIONS

1. Abdominal obesity is highly prevalent in a non-selected large cohort of patients in Primary Care practice in Portugal.
2. A higher waist circumference was significantly associated with important cardiometabolic risk factors, in both sexes.
3. Abdominal obesity – whenever present – is an additive marker of cardiovascular risk to traditional major risk factors.
4. Identification of subjects who have higher waist circumference may provide opportunities to initiate cardiovascular prevention strategies.

SPMI Porto 2006

SPEObesidade Porto 2006

SPA Algarve 2006

ACCELERATE INNOVATION FOR PATIENTS

Translational Medicine

to create deeper interaction between clinic and fundamental research and improve diagnosis and patient care.

Biotechnology partnerships

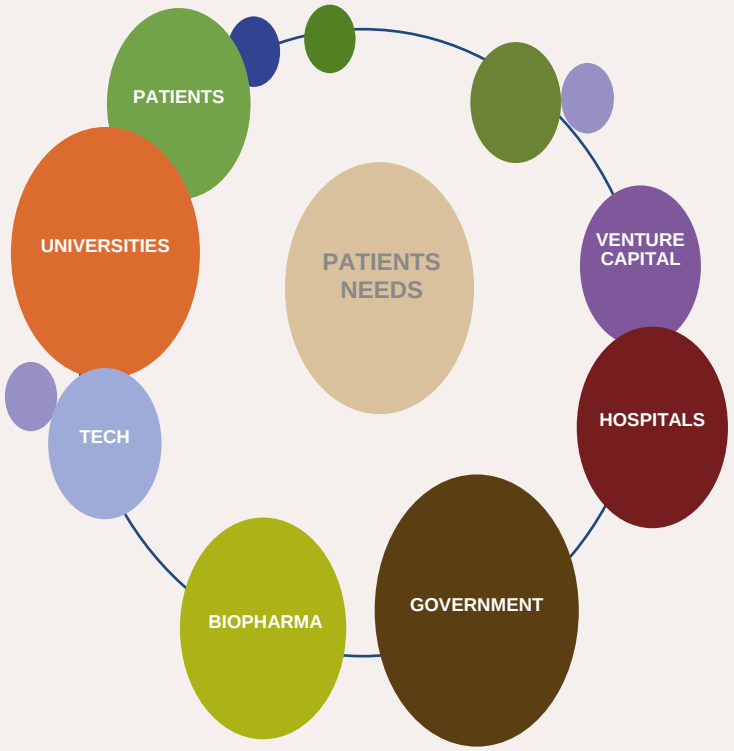
to accelerate innovation.

80%

of our development projects are biologics(1)

(1) 39 new molecular entities and vaccines of a total of 49 (source: Sanofi annual results 2013)

Open innovation



This health ecosystem places the patient and their needs at the heart of the priorities.