

# **SHERE - methods in patient-centered outcomes and health research**

Rapport Hcéres

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# HCERES

High Council for the Evaluation of Research  
and Higher Education

Research units

HCERES report on interdisciplinary  
research unit:

methodS in Patient-centered outcomes and HHealth  
ResEarch  
SPHERE

Under the supervision of the following  
institutions and research bodies:

Université de Nantes

Institut National de la Sante Et de la Recherche

Médicale - INSERM

Université François-Rabelais de Tours

# HCERES

High Council for the Evaluation of Research  
and Higher Education

Research units

*In the name of HCERES,<sup>1</sup>*

Michel Cosnard, president

*In the name of the experts committee,<sup>2</sup>*

John Browne, chairman of the committee

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Under the decree N°2014-1365 dated 14 november 2014,

<sup>1</sup> The president of HCERES "countersigns the evaluation reports set up by the experts committees and signed by their chairman." (Article 8, paragraph 5)

<sup>2</sup> The evaluation reports "are signed by the chairman of the expert committee". (Article 11, paragraph 2)

## Evaluation report

This report is the sole result of evaluation by the expert committee, the composition of which is specified below.  
The assessments contained herein are the expression of an independent and collegial reviewing by the committee.

|  |   |
|--|---|
| Unit name:                             | methodS in Patient-centered outcomes and HHealth ResEarch |
| Unit acronym:                          | SPHERE  |
| Label requested:                       | Inserm  |
| Current number:                        | EA 4275   |
| Name of Director<br>(2015-2016):       | Ms Véronique SEBILLE                                      |
| Name of Project Leader<br>(2017-2021): | Ms Véronique SEBILLE                                      |

## Expert committee members

|   |  |
|---|--|
| Chair:  | Mr John BROWNE, University College Cork, Ireland   |
| Experts:  | Mr Paul LANDAIS, Université de Montpellier<br>Mr Louis Rachid SALMI, Université de Bordeaux (representative of the INSERM)   |
| Scientific delegate representing the HCERES:            | Mr Emmanuel LAGARDE  |
| Representatives of supervising institutions and bodies: | Mr Frédéric BENHAMOU, Université de Nantes<br>Ms Anne-Claire DE REBOUL, CHU de Nantes<br>Ms Marianne DESMEDTS, INSERM délégation régionale<br>Ms Virginie FERRE, Université de Nantes<br>Ms Christine GUILLARD, INSERM<br>Mr Olivier LABOUX, Université de Nantes<br>Mr Emmanuel LESIGNE, Université François-Rabelais de Tours<br>Ms Violaine MIZZI, CHU de Tours |
| Head of Doctoral School:                                | Ms Corinne MIRAL, Doctoral School n° 502, ED BS “Biologie et Santé”  |

## 1 • Introduction

### History and geographical location of the unit

The EA 4275 SPHERE (bioStatistics, Pharmaco-epidemiology and Human sciEnces ResEarch) unit is located at the University of Nantes and was created *de novo* in 2008. It was thereafter renewed in 2012. It brings together researchers from different disciplines: Biostatistics, Psychiatry-Addictology, Pharmacology, Health Psychology and Economics. It aims at developing biostatistical, methodological, and epidemiological expertise in the fields of Patient-Reported Outcomes (PRO) measures, pharmacological and clinical approaches in pharmaco-dependence and addictive disorders, and prognostic.

The unit is member of the “Federative Structure of Research (SFR) Health” François Bonamy - EDF 4203 / UMS 016 Inserm / CNRS 3556, which brings altogether the research laboratories in Nantes working in the field of health, under the tutelage of the University of Nantes, Inserm, CNRS and the Nantes University Hospital.

For the next quinquennium, the unit will be a merger between the unit created in Nantes and another unit from Tours (François Rabelais University and University Hospital). Most of Tour unit members were part of - or collaborated with - the METHODS team (Therapeutic Evaluation Methods for Chronic Diseases) of the INSERM Center of Research in Epidemiology and Statistics Sorbonne Paris Cité - CRESSS U1153. And their main research topics were pragmatic clinical trials and notably cluster randomized trials.

The new unit will therefore be located both in Nantes and in Tours.

### Management team

The unit is directed by Ms Véronique SEBILLE, professor. In the new configuration, Ms Véronique SEBILLE will be assisted by Mr Bruno GIRAudeau, professor, who will act as deputy director in Tours.

### HCERES nomenclature

Domaine disciplinaire principal : SVE1\_LS7 Epidémiologie, Santé Publique, Recherche Clinique, Technologies Biomédicales

Domaine disciplinaire secondaire : SHS1\_1 Economie

Domaine disciplinaire secondaire : SHS4\_Psychologie

### Scientific domains

Biostatistics and psychometrics, health economics and psychological analyses of PRO measures, pharmacological and clinical approaches in pharmaco-dependence and addictive disorders.

## Unit workforce

| Unit workforce  | Number as of 30/06/2015 | Number as of 01/01/2017 |
|---|-------------------------|-------------------------|
| N1: Permanent professors and similar positions  | 12                      | 17                      |
| N2: Permanent researchers from Institutions and similar positions   |                         | 1*                      |
| N3: Other permanent staff (technicians and administrative personnel)  | 1(0.5)                  | 3(1.0)                  |
| N4: Other professors (Emeritus Professor, on-contract Professor, etc.)                                      | 1(0.3)                  |                         |
| N5: Other researchers from Institutions (Emeritus Research Director, Postdoctoral students, visitors, etc.) | 5 (0.8)                 |                         |
| N6: Other contractual staff (technicians and administrative personnel)                                      | 2(0.3)**                |                         |
| N7: PhD students  | 13                      |                         |
| <b>TOTAL N1 to N7</b>   | <b>34</b>               |                         |
| Qualified research supervisors (HDR) or similar positions   | 8                       |                         |

\*: University Research Engineer

\*\*: University Hospital Study Engineer

\*\*\*: including PhD Theses that should be defended in 2016.

| Unit record   | From 01/01/2010 to 30/06/2015 |
|---|-------------------------------|
| PhD theses defended   | 9                             |
| Postdoctoral scientists having spent at least 12 months in the unit           | 2                             |
| Number of Research Supervisor Qualifications (HDR) obtained during the period | 4                             |

## 2 • Overall assessment of the interdisciplinary unit

### Introduction

Using publications as a guide the main interests of the unit are psychometrics, clinical epidemiology, addiction studies, pharmacology/pharmaco-epidemiology and biostatistics. A further interest is prognostic modelling of chronic disease but this is mostly focused on kidney transplantation. A lot of the work is methodological in nature. The unit in Tours seems to have more of a practical focus, with a lot of specific clinical questions being addressed by original research or reviews. The combination of the two units would be a nice balance of practical and methodological work; however the specialty interests of the two units are not identical - e.g. Tours has an interest in Dermatology which does not match with Nantes' interests.

The general objectives proposed for the future remain generally methodological in nature and it would be helpful to articulate the particular societal challenges the proposed unit aims to address. From a strategic perspective, the unit is very well positioned to support the investigation of applied biostatistical research that aims to improve clinical decision making.

### Global assessment of the unit

Both Nantes and Tour unit are very productive. The average output of the researchers is prolific. 349 peer-reviewed publications have been produced in the 2010-2015 period (6.2 publications per full-time equivalent), 43% (152) were signed as first, second or last author, with a significant contribution in methodological journals (Stat Med, BMC Med Res Methodol, Qual Life Res, Stat Methods Med Res, Epidemiology, J Clin Epidemiol, Biostatistics, J Biopharm Stat, J Gamble Study). The unit is also particularly skilled at generating funding. The combined teams have received 44 grants (38 Nantes - 6 Tours) mainly from national agencies.

The researchers at Nantes have generally focused on methodological issues and this could be balanced with an increased focus on applied research that can be translated for patient benefit.

The training in biostatistics and epidemiology offered by the Nantes unit is generally satisfactory but the doctoral students would benefit from being linked into training schemes which expose them to other disciplinary perspectives (e.g. population health, health services, health policy, health economics). There is a risk that the current students will only be comfortable working within their disciplinary boundaries. The Nantes group provides a great public service by training future biostatisticians who are in short supply, but they must be capable of addressing a broad range of issues, not just narrow methodological issues.

### Strengths and opportunities in the context

The individual researchers at both Nantes and Tours are clearly hard working and productive within the specific fields they operate in. The researchers at Nantes have an excellent track record at raising research funds. There is evidence of a commitment to interdisciplinary research. The researchers have national and international respect. Some of the researchers are producing cutting-edge research that is at the forefront of the field. There is great potential within both teams if properly oriented towards important societal challenges. The researchers at both Nantes and Tours seem well integrated into the local academic and clinical environment. The Nantes team is deeply committed to training by research. There is a good commitment of the institutions which helped to create several types of position: Maître de Conférence (MCF), promotion of Hospital Practitioner (PH) to University Professor (PU-PH), promotion of MCF to professor, promotion of teaching and research temporary assistant (ATER to MCF), and also helped by providing the access to the BIRD computing centre and as well as a future location in a new research building (IRS2).

### Weaknesses and threats in the context

The focus of researchers at Nantes and, to a lesser extent, at Tours is methodological and this presents a somewhat unbalanced profile.

The training opportunities available to PhD students at Nantes are limited in some areas.

The plans presented for the future make slight reference to the new team from Tours. It is not clear how they will contribute to the three proposed 'axes'.

There is a danger of relying on a small number of senior researchers to provide the strategic direction of the Unit. Contingency plans for dealing with the loss of these researchers should be developed.

The reliance on economics research expertise from outside organisations should be addressed in the long term.

It is unclear how the research team might belong to two doctoral schools, which is not generally allowed.

The strategic management of the merged unit on two distant geographic sites may be difficult in the future.

The unit lacks full-time researchers and support staff.

### Recommendations

If the unit is to become internationally recognised and appealing to funding agencies and to attract students and young researchers, the committee recommends that it focuses on a small number of strategic areas. One possibility is to clearly brand the unit as a centre of excellence for biostatistical research as applied to clinical decision making.

In the future, there should be a greater emphasis on the translation of research into real-world applications, and a repositioning of the unit so that it is capable of performing research that addresses major societal challenges. One way to do this might be to form an external advisory group composed of stakeholders (e.g. funding agencies, health policy makers, industries, patient groups, and healthcare providers) who are interested in using the research of the proposed unit.

Careful consideration of the risks associated with the merger of the Nantes and Tours teams should be undertaken.

The training opportunities available locally to PhD students at Nantes should be expanded, particularly in the fields of health economics and applied biostatistics.

There is a need to further integrate the work carried out by researchers in the different axes, and to assist the integration of researchers in Nantes and Tours into one team.