CONSTANCES CHARTER

This document sets forth the rights and responsibilities of the research teams associated with the CONSTANCES cohort. It reviews the institutional environment of CONSTANCES and its governing bodies and then specifies the stages and requirements of research projects associated with the cohort.

- Procedures for project selection
- Conditions for using cohort data
- Procedures for the collection and use of and access to data collected in supplementary investigations
- Funding of research projects associated with the cohort
- Scientific responsibilities
- Data protection
- Dissemination of research results
- Declaration of agreement to comply with the operating rules

PROCEDURES FOR ACCESS BY THE SCIENTIFIC COMMUNITY

January 2014

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RÉPUBLIQUE FRANÇAISE
MINISTÈRE DES AFFAIRES SOCIALES ET DE LA SANTÉ

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The *CONSTANCES* project is conducted as a partnership between the National Health Insurance Fund (*Caisse nationale d'assurance maladie*, CNAMTS) and its Health Screening Centres (HSC), the National Retirement Fund (*Caisse nationale d'assurance vieillesse*, CNAV), the National Institute of Health and Medical Research (*Institut national de la santé et de la recherche médicale*, INSERM) and the University of Saint Quentin en Yvelines (*Université de Saint Quentin en Yvelines*, UVSQ), and supported by the Ministry of Health (*Direction générale de la santé*). Its scientific and technical direction is provided by the INSERM-UVSQ *"Population-based Cohorts Unit"*.

As part of the French project for coordination of research platforms and the development of large biomedical cohorts (PREDECOB) from the roadmap for very large research infrastructures (*Très Grandes Infrastructures de Recherche*), the Ministries of Education and of Health (*Direction Générale de la Recherche et de l'Innovation* of the *Ministère de l'Enseignement Supérieur et de la Recherche* and the *Direction Générale de la Santé* of the *Ministère de la Santé*) set up a procedure to select the cohorts to receive funding. They must be national infrastructures that can fit into larger or more complex international infrastructures. A very large research infrastructure (TGIR) is a tool set up to conduct research that is important in itself and that can also provide services to one or several large scientific communities. The cost of its construction and operation is such that it justifies a concerted decision-making process for its funding at the national level and even at European or international level and that is requires multiyear planning. Its governance is centralised and its orientations and evaluation managed by a high-level Scientific Committee. Access to it is open to all, on the basis of scientific excellence.

During the 2007-2009 period the *CONSTANCES* cohort received fundings from the Ministry of Health, during the 2010-2012 period, from the National Cohort Coordinating Committee (*Cellule de Coordination Nationale des Cohortes*), created for this purpose and managed by IReSP within INSERM's Institute of Public Health-ISP. Since 2012, *CONSTANCES* is an "*Infrastructure nationale en biologie et santé*" and benefits from a grant from the National Research Agency (*Agence nationale de la recherche*, ANR).

1 GOVERNANCE OF THE CONSTANCES COHORT

The cohort is implemented and managed by the *"Population-based Epidemiologic Cohorts Unit"*, a joint INSERM-UVSQ Unit. The head of this Unit is the Director of *CONSTANCES.*

The governing bodies of the *CONSTANCES* cohort are:

- The Institutional Steering Committee (ISC), which is the body that directs the project. It brings together all of the institutions that supports the *CONSTANCES* cohort. It makes or ratifies all major decisions. The composition of the *CONSTANCES* Institutional Steering Committee is listed in the appendix to this document
- The International Scientific Committee, which helps to make the decisions about scientific choices, especially of research projects and their contents. Where appropriate, it resolves any possible conflicts of interest between directors of research projects associated with the cohort. The composition of the *CONSTANCES* Scientific Committee is listed in the appendix to this document.
- The Internal Scientific Committee is composed of researchers specialized in the main scientific topics of *CONSTANCES*, involved in ancillary projects within the cohort. It gives scientific advices to the team in charge of *CONSTANCES*, and helps in establishing links with the French and international scientific community. The composition of the *CONSTANCES* Internal Scientific Committee is listed in the appendix to this document.
- The Ethics Committee, which helps to define the correct application of regulations related to the protection of cohort members and their data. Currently, the INSERM Ethics Committee serves as the *CONSTANCES* Ethics Committee.

There is also an Internal Scientific Committee composed of researchers specialized in the main scientific topics of CONSTANCES, involved in ancillary projects within the cohort. It gives scientific advices to the team in charge of CONSTANCES, and helps in establishing links with the French and international scientific community.

2 PROCEDURES FOR RESEARCH PROJECTS ASSOCIATED WITH THE CONSTANCES COHORT

2.1 SELECTION OF RESEARCH PROJECTS BY GOVERNING BODIES OF THE CONSTANCES COHORT

All research teams, French or foreign, that wish to use the *CONSTANCES* cohort must submit an application to the cohort ISC. It may involve the use of available data as well as the biological materials collected, and/or the collection of supplementary data for a specific objective. Public calls for research projects will be issued twice a year.

IMPORTANT NOTE: the research teams that participated in developing the CONSTANCES cohort protocol have a period of 6 months from the publication of the Call for Projects during which they have an exclusive right to propose a research project.

2.1.1 Content of the application

An application describing the scientific and methodological aspects of the project, its potential implications in terms of confidentiality, ethics and good professional practices, as well as its funding, must be submitted to the *CONSTANCES* cohort ISC. This application will include a preliminary study schedule, from its beginning. The Call for Projects and application form can be downloaded from the *CONSTANCES* website (www.constances.fr).

2.1.2 Examination of the application

It includes the following stages:

1. Technical examination by the *CONSTANCES* cohort team (of feasibility, confidentiality, consistency, etc.); if the project plans for the collection of supplementary data, special attention will be paid to the procedures for its collection, their compliance with existing guidelines, their complementarity with already recorded data and to the procedures for contacting cohort's participants. Where appropriate, the CONSTANCES team will provide technical support for setting up the project. The conclusions of the technical examination of the application will be transmitted to the Scientific Committee.
2. Scientific and methodological examination (interest, quality, etc.) by the *CONSTANCES* International Scientific Committee. The modalities of this review are the following:
    a. Evaluation criteria: scientific and methodological quality of the project; competition with a current or already planned project; adequacy of the project to the general long-term coherence of *CONSTANCES* (repeated contacts with the participants, redundancy with existing data); ethical aspects.
    b. Projects already evaluated by other scientific committees: if the feasibility is granted by the the *CONSTANCES* team, the International Scientific Committee does not evaluate it again and transmit he application to the ISC, except if the *CONSTANCES* team judges that there are some concerns about a negative impact on the general long-term coherence of *CONSTANCES.*
    c. Procedures: two members of the International Scientific Committee examine the application; they can ask an advice from external reviewers. They report to the full Scientific Committee who transmits its evaluation to the ISC.
3. On request of the Director of *CONSTANCES*, the International Scientific Committee or the ISC, the application may be transmitted to the Ethics Committee for its advice.
4. Authorisation by the ISC: comments of a technical, methodological, scientific and, where appropriate, ethical nature will be transmitted to the *CONSTANCES* ISC, which will approve or reject the proposal and inform the applicant of its decision.

This procedure must not take more than 3 months from the closing of the Call for Projects. This deadline may be extended if the Director of *Constances*, the Scientific Committee or the ISC ask for additional information to the applicant. Once a year, an account of all applications and of the decisions of the ISC is given to the Scientific Committee.

Note: If the project is a request of the health authorities, which requires a period of rapid implementation, an expedited procedure will be established to examine the application in a timescale compatible with the authorities' request.

2.2 LEGAL AUTHORISATIONS

Confidentiality: as part of the examination of a study application that requires or allows the identification of subjects, the applicant must request approval from the CNIL (National Data Protection Authority, *Commission nationale de l'Informatiques et des Libertés*), and its approval must be submitted with the application. If the CNIL application has not yet been submitted, the ISC may approve the study application subject to CNIL authorisation, but no data can be transmitted before this authorisation is received.

Ethics: if the project includes items that might require the opinion of an Ethics Committee or Committee for the Protection of Persons Involved in Biomedical Research-CPP, the applicant must request this Committee's approval and attach it to the application. If genetic data is to be

transferred, authorisation by the specific competent authorities must be obtained in advance and attached to the application.

2.3 DATA PROTECTION

It is the responsibility of the *CONSTANCES* Director and each research project director to ensure the technical security of the data and compliance with confidentiality and to enumerate the precautions taken to avoid the direct or indirect identification of subjects.

2.4 MEMORANDUM OF AGREEMENT

When a research project is accepted, the specific modalities of the collaboration between the *CONSTANCES* cohort team and the applicant team must be recorded in the form of a memorandum that must be transmitted to the ISC. The Memorandum must specify the following points, in particular:

- definition of the sample concerned;
- list of the variables to be transmitted (made available by the *CONSTANCES* team from a data catalogue);
- duration of the project, frequency and modalities of transfer (name and contact information of recipient);
- procedures for data protection;
- confidentiality clauses;
- exclusivity-of-use clauses (if pertinent);
- clauses concerning the provision of supplementary data collected as part of the proposal, including the format of the associated documentation and the exclusivity-of-use period (if pertinent);
- modalities of project follow-up, including the possibility to stop the project before its planned ending by decision of the investigators, or of the ISC based on the advice of the Scientific or the Ethics Committees; a clause may imply compulsory transmission of already collected data to the *CONSTANCES* Director;
- modalities of communication of results;
- rules concerning publication;
- financial clauses;
- appendices: copy of regulatory opinions and authorisations; copy of the advice of the Scientific Committee and, where appropriate, of the Ethics Committee, and ISC authorisation; declaration of agreement to comply with the *CONSTANCES* Charter, commitment of destruction of data transmitted at the end of the project.

2.5 ACCESS TO DATA: RESEARCH PROJECTS SEEKING TO USE DATA AVAILABLE IN THE CONSTANCES DATABASE WITHOUT THE COLLECTION OF SUPPLEMENTARY INFORMATION

Subject to problems of confidentiality, ethics, professional practices, or property, all data collected by the *CONSTANCES* team and contained in the cohort database can be transmitted to researchers whose proposal has been accepted, except in the case of a specific contrary decision by the *CONSTANCES* International Scientific Committee, Ethics Committee or ISC. The *CONSTANCES* team will prepare, in collaboration with the requesting team, the data selected and supply them in the most appropriate form, as a function of the technical possibilities at the time.

In the absence of an explicit prior agreement, only the director of the research project that seeks to use *CONSTANCES* cohort is authorised to request data from the cohort team.

The analyses must cover only those topics specified in the research project's application. Accordingly, only the data specifically planned in the application can be requested. In the case of a major extension of the initial project, a new application must be filled.

The transfer of data supplied by the *CONSTANCES* team to any person other than those foreseen in the application is forbidden. At the conclusion of the study, the research project director must no longer use the data file supplied by the *CONSTANCES* team and have to destroy these data. The *CONSTANCES* ISC may consent to the use of the data beyond the planned study end date if the delay was justified.

Particular case of genetic data: because this type of data is governed by specific legislative and regulatory provisions, projects intended to use it must comply with the specific conditions applicable at the time of application; in particular, it may be necessary to obtain written informed consent specific to this project, signed by the subjects concerned (or their representative). The application must enumerate all measures taken to comply with these dispositions.

2.6 ACCESS TO DATA: RESEARCH PROJECTS INVOLVING THE COLLECTION OF SUPPLEMENTARY DATA

2.6.1 Modalities for the collection and safeguarding of the new data

Beyond the data collected by the *CONSTANCES* cohort team during normal cohort operations, supplementary data may be collected by investigators whose research projects are accepted by the *CONSTANCES* cohort ISC. These data may be collected by questionnaires sent to participants either by the associated project investigator or included in the annual questionnaires sent by the *CONSTANCES* cohort team, or by any other method authorised by the competent authorities, with the agreement of the participants concerned. If the research project requires direct access (interview, examination, etc.) to cohort members, the operational aspects of this access must be defined in detail in the research project protocol submitted to the ISC.

In the case of such a need, all precautions concerning potential authorisations, confidentiality, ethics, and professional practices must be complied with and described in the application form.

No other information can be requested from cohort members other than that explicitly authorised as part of the research project accepted by the *CONSTANCES* ISC. A copy of all correspondence to the cohort members must be transmitted before it is sent to the *CONSTANCES* cohort team for its approval.

Data specific to the associated research project team and collected directly by its investigators belong to it, and it is responsible for conserving it. Nonetheless, after an appropriate period of exclusive use after the end of collection of data (set by written agreement in the above mentioned agreement memorandum), the investigator of the research project associated with the cohort agrees that the new data will be incorporated into the overall *CONSTANCES* database, in a usable form and accompanied by adequate documentation. During this data transfer, the investigator who has collected these new data shall renounce all rights to them. The *CONSTANCES* Director may decide to not include these data in the cohort database if there is some concern with their quality.

The *CONSTANCES* cohort team may also regularly request a copy of the data files collected by the investigator, accompanied by adequate documentation for the sole purpose of safeguarding and archiving it. The *CONSTANCES* team agrees not to use these data in any way and not to transmit them to anyone else without the formal agreement of the principal investigator of the associated research project. The *CONSTANCES* team will have no role in the management of these data, and the principal investigators of the associated projects shall remain solely responsible for them.

2.6.2 Modalities of access by other researchers to data collected by projects that conducted supplementary investigations

One of the advantages of the openness of the *CONSTANCES* cohort to the scientific community is the possibility of mutualising the data about cohort members from the different research

projects associated with this cohort. Access by researchers managing a project within *CONSTANCES* to new data collected by the directors of other associated projects is therefore encouraged. The rules of access will differ depending on the specific case.

a) **Data catalogue**: each director of a project involving the collection of specific data agrees to create at the start of the project and regularly update a data catalogue modelled on that of the *CONSTANCES* cohort. The *CONSTANCES* team shall keep a regularly updated catalogue of exterior data, organised by project, to facilitate links between researchers.

b) **Use of the new data transferred to the *CONSTANCES* cohort team after the exclusive-use period has expired**: on transfer of these new data to the *CONSTANCES* team, the investigator who collected them shall renounce all rights to them. These data can then be used by all researchers, according to the rules set forth above.

c) **Use of these new data during the exclusive-use period by investigators of associated research projects**:

Two different situations may occur.

- Requested data are **not original** (published scales or questionnaires used in the project). Again, there are two situations:
    - Data were collected by the *CONSTANCES* team (usually through the annual questionnaire): in such a case, the *CONSTANCES* Director takes the decision after informing the investigators who first introduced these data. He may ask an advice from the International Scientific Committee or of the Ethics Committee.
    - Data were collected by the investigator of the research project (funding, data entry and validation…): in such cases, the rules are the same as it data were original (see below).
- Requested data are **original** (questionnaire elaborated by the investigator, medical exams…): during the exclusive-use period, only the investigators of the associated projects can decide whether or not to transmit the original data they collected or about any other arrangements they might want between themselves and another team requesting access. When they agree, a document must be drawn up specifying the data to be transferred and their planned utilisation. A copy of this document must be transmitted to the *CONSTANCES* Director. Once the project team directors have made the decisions about data transfers, these transfers must go through the *CONSTANCES* team, which can thus keep the status of all the cohort data up to date. The intermediary role of the *Constances* team is also made necessary by the system chosen to protect the subjects' anonymity in the database.

In all cases when a project uses data provided by another teams, the researchers who provided the data must be acknowledged in the publications.

2.7 FOLLOW-UP OF RESEARCH PROJECTS

Project progress reports must be regularly supplied to the *CONSTANCES* team. The format and timing of these rapports are specified in the document cited in § 2.2.4. They may be transmitted to the International Scientific Committee, which can when appropriate recommend to the ISC that the project be cancelled. In the latter case, the ISC can ask the transmission of already collected data to the *CONSTANCES* Director for integration in the cohort's database; these data can then be used by any researcher according to the same rules as the data collected by the *CONSTANCES* team.

IMPORTANT NOTE: projects planning a very long follow-up will be assessed again very 5 years by the Scientific Committee.

2.8 FUNDING OF RESEARCH PROJECTS ASSOCIATED WITH THE CONSTANCES COHORT

The costs of the work performed by the *CONSTANCES* cohort team to provide data to the investigator are assessed on a case-by-case basis and enumerated in the document describing the modes of collaboration between it and the research project team, transmitted to the ISC, as mentioned in § 2.2.4.

The specific costs related to the research project (potential collection of additional data, data analysis, etc.) shall be borne by the associated research project. Where appropriate, the *CONSTANCES* cohort team can provide methodological support for obtaining funding from other sources. **Applications to funding bodies must include the costs of the work performed by the *CONSTANCES* cohort team, and no application can be made without the written agreement of the *CONSTANCES* Director.**

2.9 SCIENTIFIC RESPONSIBILITIES

2.9.1 Scientific responsibility of the CONSTANCES team

The *CONSTANCES* cohort team agrees to comply with the cohort protocol as validated by the International Scientific Committee; modifications of the protocol must be approved by the International Scientific Committee. The team is the intellectual property holder of the conception and execution of the basic structure as well as the formulation of the scientific hypotheses that made it possible to set up and follow up this cohort. The *CONSTANCES* Director and team are also responsible for the methods used to transport and store the biological materials collected and for their use solely for research purposes.

The *CONSTANCES* cohort Director and team are responsible from a scientific perspective for the quality of the data collected (its exhaustiveness and validity) and for the verification of its consistency. The quality assurance protocol and the procedures for implementation and management of the database are to be made available to all research teams that so request.

2.9.2 Scientific responsibility of research project teams

The directors of the various research projects hold the intellectual property relative to their projects. They are responsible for the statistical treatment and analyses of these data, their scientific publication and all other dissemination of the results, in compliance with good epidemiological practices. In the case of supplementary data collection, the director of each research project undertakes to comply with the good practice recommendations of international learned societies, when these exist, and to provide to the *CONSTANCES* Director all the information needed to assess the quality of the data in order to decide whether they can be included in the *CONSTANCES* database.

2.10 DISSEMINATION OF RESEARCH RESULTS

2.10.1 Scientific publications

The results from the projects using Constances data must be made public through publication in scientific journals, reports, thesis, etc. If needed, a confidentiality period can be defined in the memorandum of agreement. Directors of research project can publish their results and thus provide the scientific community with this information in any form they choose. They are entirely responsible for such publication and must take into account the standard professional practice rules in this area.

Directors of research projects are required to provide a copy of each manuscript to the *CONSTANCES* Director at the moment of submission; the latter can require the inclusion in the manuscript of a statement that she is not responsible for the data analysis or the interpretation of the results.

Because of the very substantial scientific and technical activity of the *CONSTANCES* team in the development and management of the cohort, the signature of at least one member of the team must appear in any scientific publication or communication from these research projects, in compliance with the standard rules, as set forth in the *Recommendations for Professional standards and good epidemiological practices (see 2.2.11 for the reference)*; these modalities shall be specified on a case-by-case basis between the project director and the *CONSTANCES* cohort Director.

A statement that the research was conducted in the *CONSTANCES* cohort must be included in every scientific publication or communication and the word "*CONSTANCES*" must appear in the title of every publication.

After publication, research project directors are required to provide to the *CONSTANCES* cohort a copy of all publications and reports resulting from the project.

2.10.2 Acknowledgements

The standard acknowledgements concerning *CONSTANCES* are as follows:

> The authors thank the INSERM-Versailles Saint Quentin en Yvelines University *"Population-based Epidemiologic Cohorts Unit" (Cohortes épidémiologiques en population*) which designed and manages the Constances Cohort Study. They also thank the National Health Insurance Fund ("*Caisse nationale d'assurance maladie des travailleurs salaries*", CNAMTS) and its health screening centres ("*Centres d'examens de santé*"), which are collecting a large part of the data, as well as the National Retirement Fund (*Caisse nationale d'assurance vieillesse),* ClinSearch, Asqualab and Eurocell, which are conducting the data quality control. The *CONSTANCES* Cohort Study was funded by the National Health Insurance Fund (*Caisse nationale d'assurance maladie des travailleurs salaries*, CNAMTS), the Ministry of Health, the Council of the Ile de France Region, and by the Cohorts TGIR IReSP-ISP INSERM (*Ministère de la santé et des sports, Ministère délégué à la recherche, Institut national de la santé et de la recherche médicale, Institut national du cancer et Caisse nationale de solidarité pour l'autonomie).* The CONSTANCES Cohort Study is an « Infrastructure nationale en Biologie et Santé » and benefits from a grant from ANR (ANR-11-INBS-0002).

Nominative acknowledgements of the researchers who contributed to the development of the *CONSTANCES* cohort protocol may also be added, depending on the data used in the research project. Where appropriate, the specific role of one or several other partners may be specified.

Because the information included in the acknowledgements of publications may require modifications, it must be submitted in advance to the *CONSTANCES* Director.

2.10.3 Reference to the CONSTANCES project

Every publication must refer to at least one of the methodological articles presenting the study protocol and published by the *CONSTANCES* team. Currently, the following reference should be cited:

> Zins M, Bonenfant S, Carton M, Coeuret-Pellicer M, Guéguen A, Gourmelen J, Nachtigal M, Ozguler A, Quesnot A, Ribet C, Rodrigues G, Serrano A, Sitta R, Brigand A, Henny J, Goldberg M. The CONSTANCES Cohort: an Open Epidemiological Laboratory. *BMC Public Health* 2010; 10:479.

It is likely that other references should be cited later; it is thus useful to consult the *CONSTANCES* Director about this.

2.10.4 Dissemination to cohort volunteers and the public

The research project director is required to prepare, in liaison with the *CONSTANCES* team, documents intended to disseminate their results to the cohort volunteers and to both medical and non-medical audiences, especially via the *CONSTANCES* cohort website. At the request of the *CONSTANCES* Director, research project teams are also required to present the progress and results of their work during the annual scientific meetings of the *CONSTANCES* cohort.

No use of these results for commercial purposes, by research project directors or their financial partners, is allowed without the written agreement of the *CONSTANCES* Director, after authorisation by the ISC.

2.10.5 CONSTANCES cohort website

The *CONSTANCES* cohort website may make public some information about the director of associated research projects. This information will concern the project (title, description, keywords, publications, etc.) as well as the name and postal address of the researchers. According to French law (Law n° 78-17 dated 6 January 6, 1978, as modified in 2004), the directors of such projects have the right to access, modify, correct, and delete data concerning themselves. Given the nature of the Internet and specifically the free availability of the information provided and the inability to control use by third parties, project directors have a right to object to public dissemination of their personal data (name, address…).

2.11 GENERAL PROVISION

The directors of research projects related to the *CONSTANCES* cohort undertake to comply with the provisions about professional standards and good epidemiological practices defined in the Recommendations adopted jointly by ADELF, AEEMA, ADEREST and EPITER, approved by the French Data Protection Authority (CNIL), the National Council of Physicians, the French Advisory Committee on Ethics in Life Sciences and Health, and the Advisory Committee on Data Treatment in Health Research (version 2007, and subject to their modification. French and English versions:

http://adelf.isped.u-bordeaux2.fr/Informations/Actualit%C3%A9s/D%C3%A9ontologieetbonnespratiquesen%C3%A9pid%C3%A9miologie/tabid/534/Default.aspx).

GOVERNING BODIES OF THE CONSTANCES COHORT

(JANUARY 2014)

Institutional Steering Committee

Representatives of:

- CNAMTS, the National Health Insurance Fund (*Caisse nationale d'assurance maladie*)
- INSERM, the National Institute of Health and Medical Research (*Institut national de la santé et de la recherche médicale*,)
- UVSQ: the University of Saint Quentin en Yvelines (*Université de Saint Quentin en Yvelines*,)
- CNAV : the National Retirement Fund (*Caisse nationale d'assurance vieillesse)*
- DGS: Direction Générale de la Santé of the Ministry of Health

International Scientific Committee

- Andrieu Sandrine, Toulouse, France
- Brodin Marc, Paris, France
- Cambois Emmanuelle, Paris, France
- Clément Bruno, Rennes, France
- Desenclos Jean-Claude, Saint Maurice, France
- Fortier Isabel, Montréal, Canada
- Hémon Denis, Villejuif, France
- Kaaks Rudolf, Heidelberg, Germany
- Rodwin Victor, New York, USA
- Saracci Rodolfo, Lyon, France
- Siemiatycki Jack, Montréal, Canada (President)
- Silberman Roxane, Paris, France
- Vermeulen Roel, Utrecht, Netherland
- Weiderpass Elisabete, Stockholm, Sweden

Ethics Committee

The INSERM "*Comité d'éthique pour la recherche médicale et en santé* (Ermes)" acts as the Ethics Committee of CONSTANCES (http://www.inserm.fr/qu-est-ce-que-l-inserm/organigramme/comites/ermes)

Internal Scientific Committee

- Berr Claudine
- Czernichow Sébastien
- Descatha Alexis
- Lemogne Cédric
- Nabi Hermann
- Nadif Rachel
- Ringa Virginie