

# Biobank-based research on digestive peritoneal carcinomatosis (the BIG-RENAPE Biobank)

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## Abstract

Access to good quality biological samples is a prerequisite for high-level translational research. The BIG-RENAPE Biobank has been established by the French hyperthermic intraperitoneal chemotherapy centers involved in the management of peritoneal surface malignancies. The Biobank is a core facility aiming to support researchers who conduct studies with sample collections, both within and outside the Big-RENAPE Network.

The Biobank is certified according to NFS 96-900 and has been launched in February 2016 as a service of processing, storage and

transfer of high quality biological (plasma, serum, buffy coat) and tissue (formalin-fixed-paraffin-embedded) samples from patients with digestive peritoneal carcinomatosis. Biospecimens are collected at each stage of diagnostic and therapeutic care. The patient and his derivatives are anonymized and registered in a web database reporting disease status, treatments, surgical procedures, pathological diagnosis, quality of life's assessment and long term follow-up. All participants have given their informed consent before any sample. The Biobank was approved by the local Ethical Committee, based on the assessed compliance to French regulatory rules. The Biobank is located in the *Centre Hospitalier Lyon (SudBioTech)*, which is known to be an expert center in the management of the peritoneal carcinomatosis.

Research projects that require material stored in the Biobank are submitted by specific form and evaluated by the BIG-RENAPE Scientific Committee. A material transfer agreement is agreed with the recipient before samples are allowed to be sent from the Biobank.

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## Introduction

Biobanks should be considered as a critical cornerstone and engine for translational and clinical research.<sup>1</sup> A customized approach to peritoneal carcinomatosis of digestive origin requires a multi-disciplinary approach.<sup>2</sup> Prospective health surveys and biobanks have thus become indispensable to elucidate molecular processes and causal pathways and to translate biomedical research into real improvements in healthcare. Since management of peritoneal carcinomatosis is complex,<sup>3</sup> heterogeneous, and resistance to locoregional and systemic treatments is common, new large-scale epidemiological and clinical studies, based on - Biobanks - are required. New technological achievements have created the opportunities to explore and analyze tissues with associated clinical data for both the elaboration and testing of new hypotheses.

## Biobank focus

The main BIG-RENAPE Biobank aim is to create a large multicentric and prospective repository for biological and tissue samples, which will provide a source of materials for a wide array of health-related research studies: i) validating known and promising biomarkers; ii) identifying new predictive and prognostic factors; iii) evaluat-

ing the impact of current health care strategies; iv) standardizing diagnostic and therapeutic management through guidelines; v) developing new drugs.

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## Bioresource location

The central site of the BIG-RENAPE Biobank is located at the *SudBioTec, Hospices Civils de Lyon - Centre Hospitalier Lyon Sud*, 69495 Pierre-Benite, France (Biological Resource Centre N° BB-0033-00046).

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## Patients

Patients' disease status was: digestive peritoneal carcinomatosis with various histological subtypes.

Patients' clinical characteristics included: i) adults only; ii) males and females; iii) patients with resectable or unresectable peritoneal carcinomatosis of digestive origin; iv) ability of participants to give their informed consent.

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## Biospecimen types

Serum, plasma, buffy coat and formalin-fixed-paraffin-embedded (FFPE). Biospecimens are collected at various stages of diagnostic and therapeutic care.

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## Data and bioresource collection

Participants deemed suitable for biobanking are identified by participating clinicians in their consult or through multi-disciplinary team meetings. Potential participants are informed and subsequently give their written consent form. Only if consent is obtained, biospecimens, including tumor and/or peripheral blood are collected. The surgical specimen is analyzed by qualified pathologists thereafter tissues are sampled, fixed (FFPE) and stored securely and anonymously by the BIG-RENAPE Biobank. Demographic, pathological, clinical information and biospecimen identification are recorded electronically on a secured Web application. Contributors to the Biobank have provided a minimal data set pertaining to their biospecimens with associated protected health information to ensure that the patient's identity remains secure.

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## Source of associated data

The major source of associated data on participants is the medical record: all data from pathologist's reports, diagnoses, laboratory tests, medical and surgical procedures, medication, imaging.

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## Standard operating procedures

The quality assurance measures that have been implemented by the BIG-RENAPE Biobank include standard operating procedure for *best*

*practices*. All standard operating procedures followed are based on NFS 96-900 Quality of Biological Resource Centers (BRC) - French management system of a BRC and quality of biological resources of human and microbial origin.<sup>4-6</sup>

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## Ethical statement

The BIG-RENAPE Biobank-based research, participant information and the consent form were approved by the Ethical Committee on the April 15, 2015 (CPP Lyon Sud Est IV) and by the French National Agency for Medicine and Health Products Safety (ANSM) on the February 27, 2015. The BIG-RENAPE database has been registered with CNIL under no. DR-2016-002 in accordance with the French Law 78-17 dated January 6<sup>th</sup>, 1978 relating to data processing, files and personal freedom and privacy.

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## Release date

Biospecimens have been available to be distributed and used by the research community at large both nationally and on the international level since February 2016.

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## Category

The category included tissue and biological samples with clinical associated data.

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## Access criteria

Currently, as the BIG-RENAPE Biobank is still in the process of developing and implementing its database, researchers can request the use of biospecimens by contacting the BIG-RENAPE Biobank manager through the *Centre Hospitalier Lyon Sud*. Researchers seeking to use BIG-RENAPE Biobank specimens are required to formally apply using a prescribed application form. The application form, along with the researcher's institutional Ethical approval for the project, is submitted to the BIG-RENAPE Biobank manager who forwards the application to the BIG-RENAPE Biobank's Scientific Committee for assessment. All requests are considered both academic and commercial. Related fees vary according to source of request. The Scientific Committee evaluates all proposals based on its scientific aims, feasibility of study, potential to improve patient care, credentials in type of research, justification for amount of biospecimens requested and overall scientific merit.

If the application is approved by the scientific committee then a material transfer agreement (MTA) is issued to the researcher. An MTA is entered into in order to transfer biospecimens to another partner (commonly another university or research institution) for the purposes of that organization's own research. The MTA governs the transfer of material, including data, between the organizations and defines the rights and obligations of each in relation to custodianship, use of the biospecimens, and data arising from such use and any modifications or derivatives of the material. The BIG-RENAPE Scientific Committee reviews all MTAs received by the BIG-RENAPE Biobank. No biospecimens are sent until the MTA has been approved by the BIG-RENAPE scientific committee and signed by both organizations.

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## Major strengths

Academic and industry based researchers can count on the BIG-RENAPE Biobank to provide tumor (paraffin-embedded) and peripheral blood (serum, buffy coat and plasma) samples of high quality. The BIG-RENAPE Biobank could also provide in the future extracted RNA and DNA.

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