

# Quality Manual

---

Biological Resource Center of  
Institut Pasteur (CRBIP)

9 November 2022

# About CRBIP

---

Created in 2001, the Biological Resource Center of Institut Pasteur (CRBIP) is a biobank that brings together three entities managing collections: CIP, PCC and ICAReB-biobank. Later, in 2018, a fourth entity managing collections joins the CRBIP: the CNCM. It was created with the mission to harmonize the management of Institut Pasteur collections under a common Quality Management System (initially, NF S96-900). In 2022, a process of integration of the Virus (CVIP) and Fungi (CFIP) collections to the CIP begins. The CRBIP is located in the campus of Institut Pasteur, Paris 15.

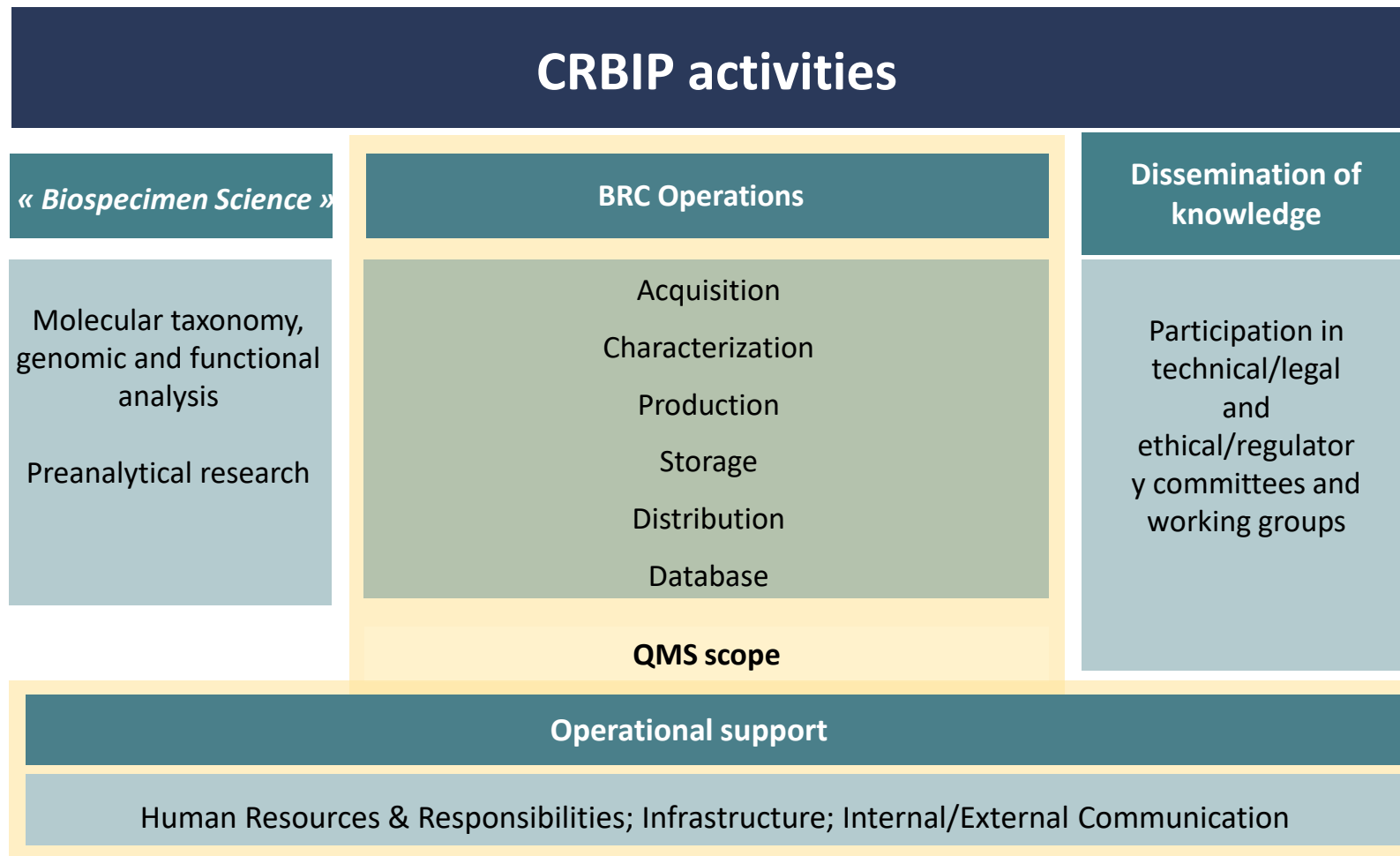
A Project Management Office (PMO) of the CRBIP has recently been formalized with a transversal role of project management - other than internal research projects - related to valorization, quality, optimization of transversal processes, communication, user relations. Entities managing collections are responsible for biobanking activities specific to their own bio-resources and for their internal research projects.

The fact that the center includes one of the first collections of microorganisms in the world, the CIP; the world reference collection for cyanobacteria, the PCC; the only IDA (International Depositary Authority) collection in France, the CNCM; as well as a collection of bio-resources of human origin, the ICAReB-biobank; and the fact that it is part of Institut Pasteur, gives the center a unique position at the national and international levels. All of this encourages us to develop a range of professional products and services, and to envisage accreditation of certain entities according to the ISO 20387 standard in 2024.

# The CRBIP Activities Organization

**Vision** : to be a reference BRC (Biological Resource Center) in the field of human diseases.

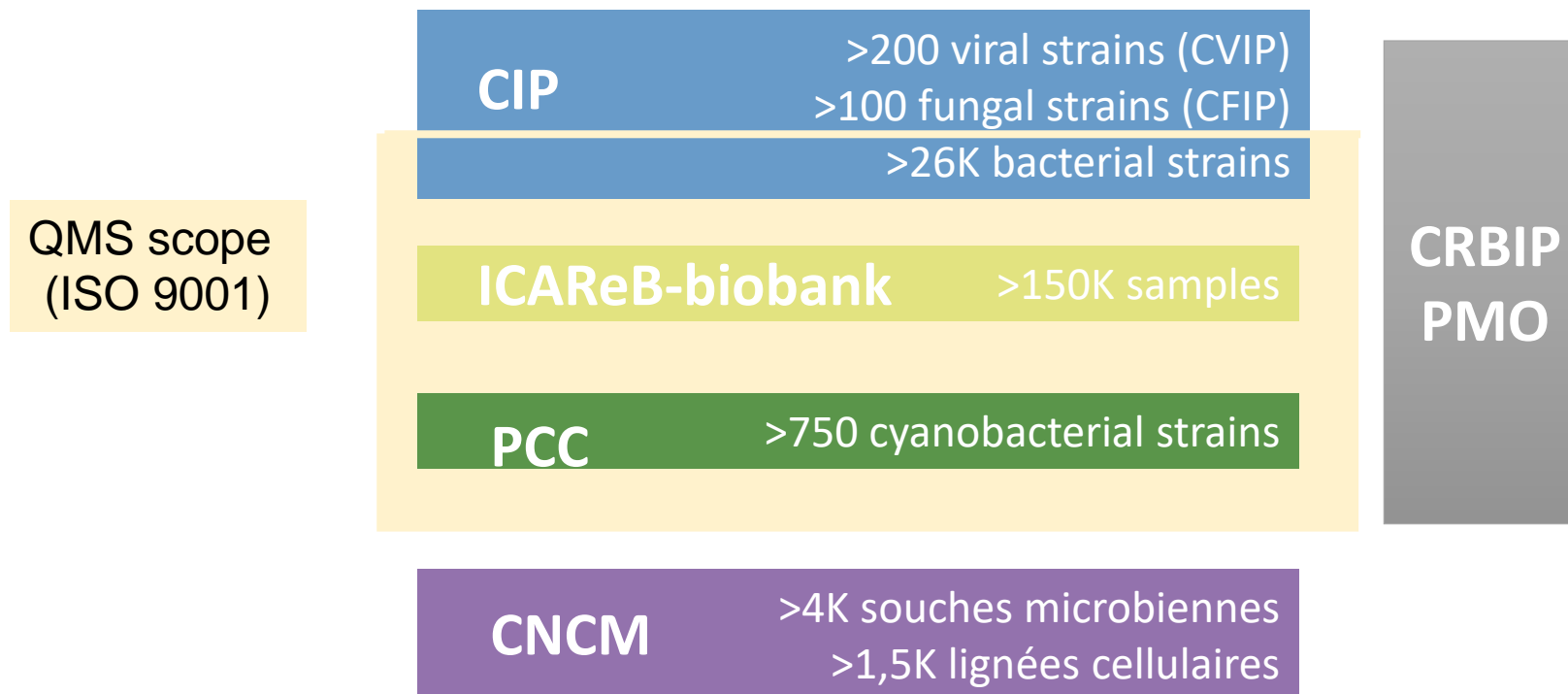
**Mission** : to preserve and provide access to qualified, historical and newly collected microbiological and human resources for research in the field of human diseases, teaching and quality control.



# The CRBIP QMS

The Quality Management System (QMS) of CRBIP covers the activities of acquisition, production or preparation, quality control or characterization, conservation and distribution of biological resources, microorganisms and human biological samples. It applies to all three entities, CIP, PCC, ICAReB-biobank.

Following the end of the certification cycle according to NF S 96-900, CRBIP will follow the ISO 9001:2015 standard while preparing the ISO 20387 accreditation. The certification target is set for CIP, PCC and ICAReB-biobank in late 2022 - early 2023. The other entities may be certified at a later date. Chapter 8.3 "Design and development of products and services" of ISO 9001 is excluded from the scope.



# The CRBIP Quality Policy

*The CRBIP Quality Policy is in line with the institutional Quality Policy.*

## Politique qualité – sécurité – développement durable de l'Institut Pasteur



Pour l'Institut Pasteur, il est impératif de répondre à ses missions de recherche, d'enseignement et de santé publique en garantissant la santé et la sécurité de ses personnels et le respect de l'environnement, dans un souci permanent de la qualité. Cette approche fait partie intégrante de sa démarche de développement durable, appelée responsabilité sociétale de l'Institut Pasteur.

Dans ce contexte, je m'engage dans le plan stratégique 2019-2023 à ce que soit intégré dans les modes de fonctionnement de l'Institut Pasteur, un haut niveau d'exigence en matière de qualité, de sécurité et plus globalement de développement durable. Cet engagement doit se traduire par :

- une parfaite maîtrise des risques qualité, sécurité et développement durable dans le déroulement des activités et des projets de l'Institut Pasteur ;
- le maintien et la mise à disposition d'un haut niveau d'expertise qualité, sécurité et développement durable au service du campus ;
- le respect de la législation et de la réglementation en lien avec la qualité, la sécurité et l'environnement ;
- la mise à disposition de tous les moyens nécessaires au respect des engagements ci-dessus.

Je confie à la direction des ressources techniques et de l'environnement :

- le déploiement de la présente politique ;
- le management rationnel des ressources qualité, sécurité et développement durable mises à disposition du campus ;
- le soin d'assurer la cohérence globale des projets de l'Institut Pasteur avec la présente politique.

J'invite tous les personnels de l'Institut Pasteur à s'engager et à contribuer activement, avec le soutien de la direction des ressources techniques et de l'environnement, à la réalisation de ces engagements et au respect de la réglementation en cohérence avec le plan stratégique de l'Institut Pasteur.

  
Stewart Cole  
Directeur général de l'Institut Pasteur

## POLITIQUE QUALITE CRBIP

Le Centre de Ressources Biologiques de l'Institut Pasteur (CRBIP) est une biobanque qui regroupe quatre entités spécialisées dans les collections de matériels biologiques (CIP, PCC, ICAReB-biobank et CNCM) qui gèrent des collections de bactéries/virus, cyanobactéries et échantillons biologiques humains, et un Project Management Office (CRBIP PMO). La mission du CRBIP est de préserver et donner accès à des ressources microbiologiques et humaines qualifiées, historiques et nouvellement collectées, prioritairement à visée de recherche dans le domaine des maladies humaines, enseignement et contrôle qualité.

Les activités du CRBIP comprennent :

- Optimisation des méthodes de préparation et biopréservation de matériaux biologiques (« biospecimen science »)
- Acquisition, préparation, contrôle qualité, conservation et distribution de ressources biologiques (opérations CRB)
- Transfert de connaissances (« knowledge dissemination »)

Seules les Opérations CRB sont concernées par la certification ISO 9001, comme c'était le cas pour la certification préalable suivant la norme NF S 96-900.

Depuis juin 2021, la CIP et ICAReB-biobank sont dans une démarche de transition vers la mise en place de la norme internationale ISO 20387 avec un objectif d'accréditation pour 2024. A court terme, la certification ISO 9001:2015 est envisagée pour la CIP, la PCC, et ICAReB-biobank.

Pour atteindre ses objectifs qualité, la Direction du CRBIP s'engage à :

- Maintenir le suivi et l'évolution du Système de Management de la Qualité au sein des trois entités engagées dans la norme ISO 9001, incluant la qualité et la conformité des matériels biologiques et des données associées ;
- Assurer la satisfaction des parties intéressées ;
- Maintenir et améliorer la communication (catalogue, site internet, enquête de satisfaction) envers celles-ci.

Je charge la Responsable Qualité du CRBIP et l'Ingénieure Qualité en charge du CRBIP (affiliée à la Direction des Ressources Techniques et de l'Environnement de l'Institut Pasteur), de coordonner les diverses tâches de mise en place et de maintien du Système de Management de la Qualité au sein du CRBIP, et de coordonner les actions avec les différents Correspondants Qualité des entités qui le composent.

Je m'engage à poursuivre cette démarche, afin de maintenir et d'améliorer le niveau de qualité du CRBIP en mobilisant tout le personnel concerné par des opérations dans le périmètre du Système de Management de la Qualité (SMQ). Également, je m'engage à réaliser une Revue de Direction annuelle afin d'établir un bilan du SMQ, de mettre à jour les objectifs et de planifier les audits qui permettront de suivre l'évolution de ce Système.

Date : 25 Octobre 2022

Fay BETSOU  
Directrice du CRBIP

Responsables des Collections du CRBIP :

Dominique CLERMONT  
CIP

Emmanuel Roux  
ICAReB - biobank

Muriel GUGGER  
PCC

## Institutional Quality Policy

## CRBIP Quality Policy



# The CRBIP Engagement

---

## **Ethics**

CRBIP is committed to respecting the ethical principles and national and international regulations applicable within its entities. To do so, CRBIP entities rely on reference texts formalized through lists of external documents, procedures and tools set up at the institutional level, such as the ethics charter or the scientific integrity committee.

## **Impartiality**

In order to guarantee the impartiality of its activities and more specifically the impartial access to its biological resources, CRBIP wished to set up an organization dedicated to this issue. A scientific committee (with a majority of external members) has been set up to ensure the impartiality of decisions taken on access requests, particularly for non-renewable resources.

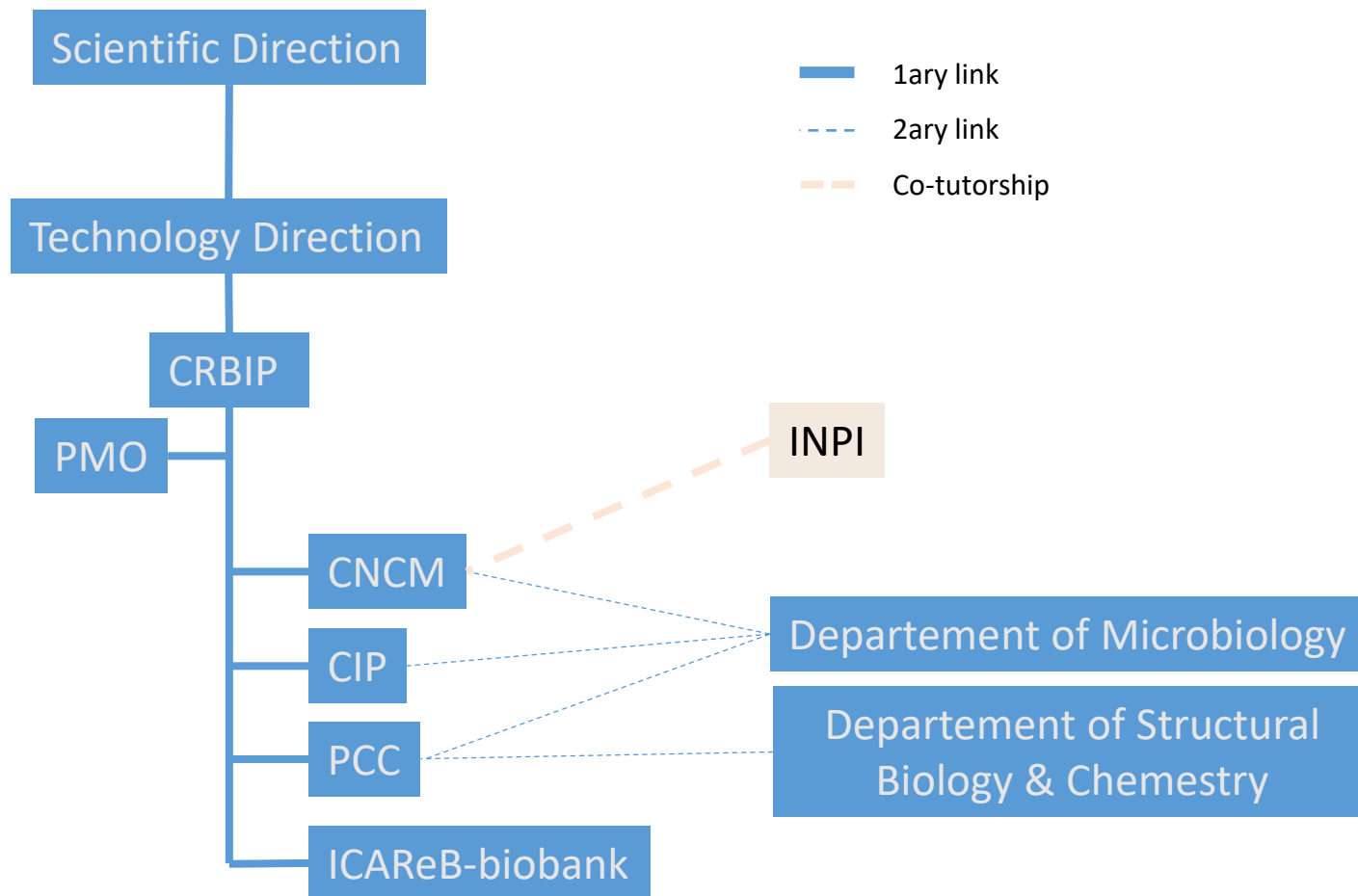
## **Confidentiality**

The staff is required, during its activities, to respect confidentiality in two main situations concerning:

- The RGPD (teams, researchers, users, donors participating in research, ...) due to personal data potentially held by some entities of CRBIP;
- Intellectual property related to biological resources or their uses.

# The CRBIP Structure

The CRBIP groups together four entities managing collections, under a single hierarchical link. A PMO is in charge of the management of CRBIP's transversal activities: quality, project set-up and management, communication, regulatory watch, etc.



# Unique site web of CRBIP : « biobanks and collections »



Since October 2019, CRBIP centralizes all information related to its BRC activities on the "biobanks and collections" website.

## Advantages of the unique CRBIP website

- General introduction on the importance of collections for research and innovation;
- Presentation of information in a harmonized manner;
- Centralization of catalogs of microorganism collections;
- Centralized information in the CRBIP tab: Regulations, training, news, etc;
- FAQ and Contact tab for each specific entity or collection.

The CRBIP oversees a group of biobanks that maintain microbial and human bio-resources, along with associated data (e.g., biological characteristics, sequence data), and make them available globally, in compliance with health and environmental safety standards and under applicable laws and regulations. The CRBIP operates under quality management certification.

#### The CRBIP's activities include:

- Reception of valuable biological material deposits.
- Characterization, preservation, and distribution of microbial and human bio-resources.
- Providing the following specialized services:
  - Acquisition and distribution of biological resources.
  - Lyophilization, production of biomass.
  - Optimized sampling and preservation methods of human bio-resources.
  - Microbial identification, sequencing, and genomics analyses.
- Offering training, expertise, and consulting services to help you to succeed in your projects and develop the skills of your teams.

→ [ABOUT CRBIP](#)

#### THE CRBIP CATALOGUE OF MICROORGANISMS



Bacterial strains and viral strains from one of the oldest culture collections in the world.

→ [READ MORE](#)

Monoclonal strain cultures representing the taxonomic and functional diversity of Cyanobacteria.

→ [READ MORE](#)

Microbial strains and cell lines deposit under the Budapest Treaty.

→ [READ MORE](#)

Samples and clinical data from patients and healthy volunteers.

→ [READ MORE](#)



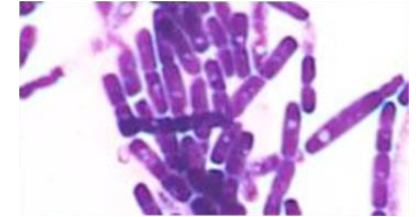
# The CIP entity

---

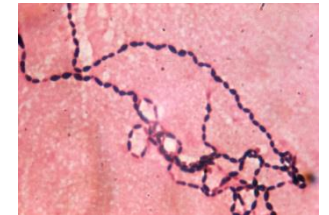


The **Collection of Institut Pasteur (CIP)** was created by Dr. Binot, who began preserving strains as early as 1891. For more than a century now, the CIP has been located on Institut Pasteur campus. Freeze-drying began at the CIP around the 1950s.

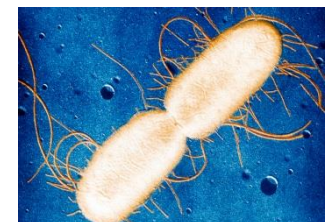
The CIP has a great biodiversity with more than 26,000 bacterial strains belonging to more than 5,000 different species.



*Bacillus*



*Streptococcus*



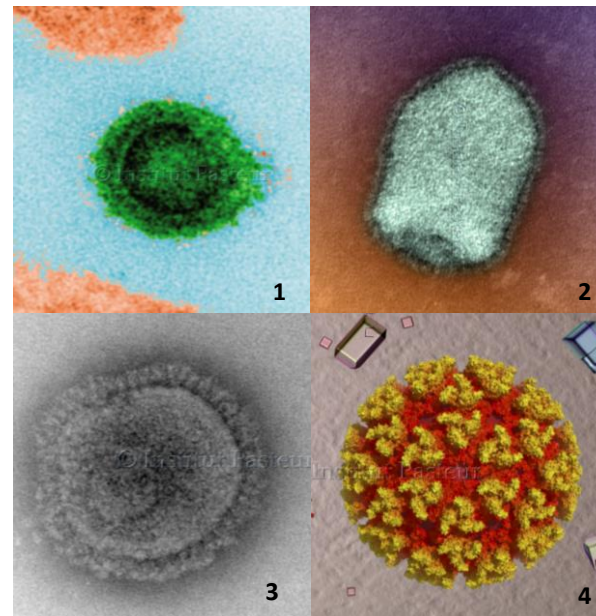
*Escherichia coli*

# The CVIP

---

The **Collection of Virus of Institut Pasteur (CVIP)** contains >200 viral strains of human origin including the families Flaviviridae, Togaviridae, Picornaviridae, Orthomyxoviridae, Rhabdoviridae and Retroviridae. Most of these viruses are stored in a frozen state, and a few are available freeze-dried.

This collection has a scientific correspondent in the Rabies NRC (National Reference Center).



- 1 Dengue
- 2 Rabies
- 3 Influenza
- 4 Chikungunya

*La CVIP fait partie de la CIP mais ne fait pas partie du périmètre de certification du CRBIP*

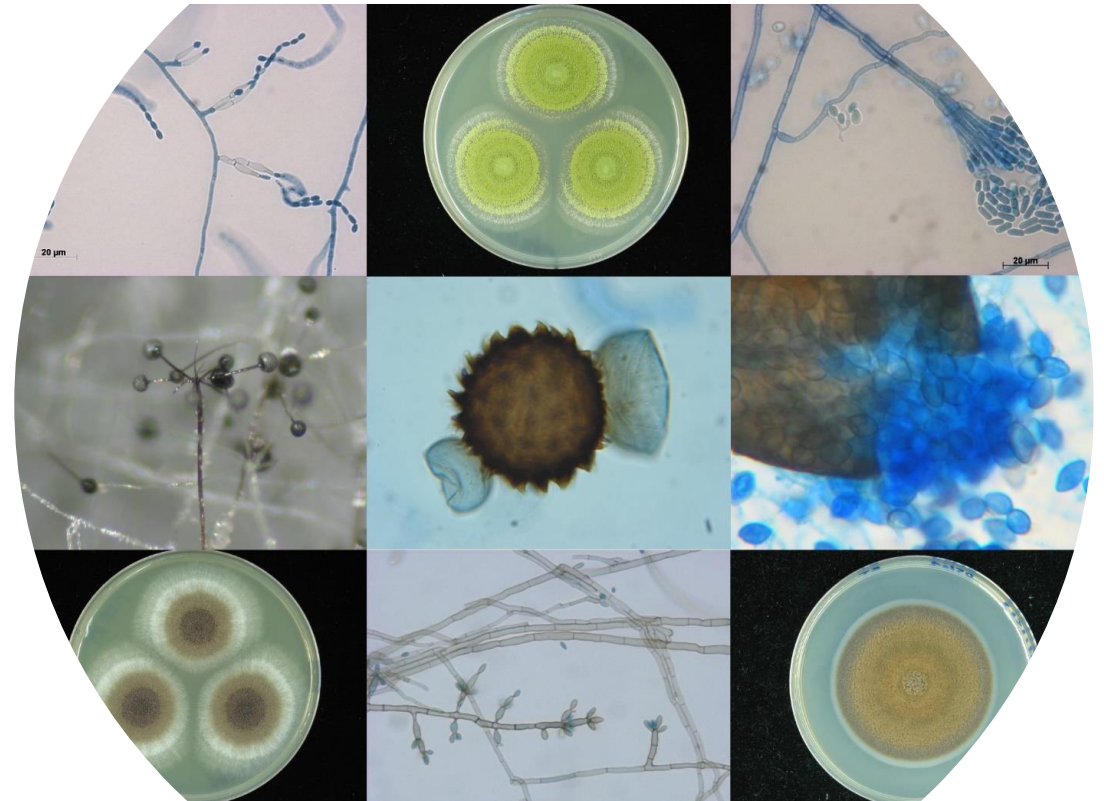
# The CFIP

---

The **Collection of Fungi of Institut Pasteur (CFIP)** aims to reintegrate the strains of yeasts and filamentous fungi (about 2000 strains) from the previous fungal collection "UMIP" at Institut Pasteur closed since 2013.

This historical collection includes specimens of different origins mainly preserved in mineral oil and in a freeze-dried state.

This collection has a scientific correspondent within the invasive mycoses NRC.



*The CFIP is part of the CIP but is not part of the CRBIP certification scope*

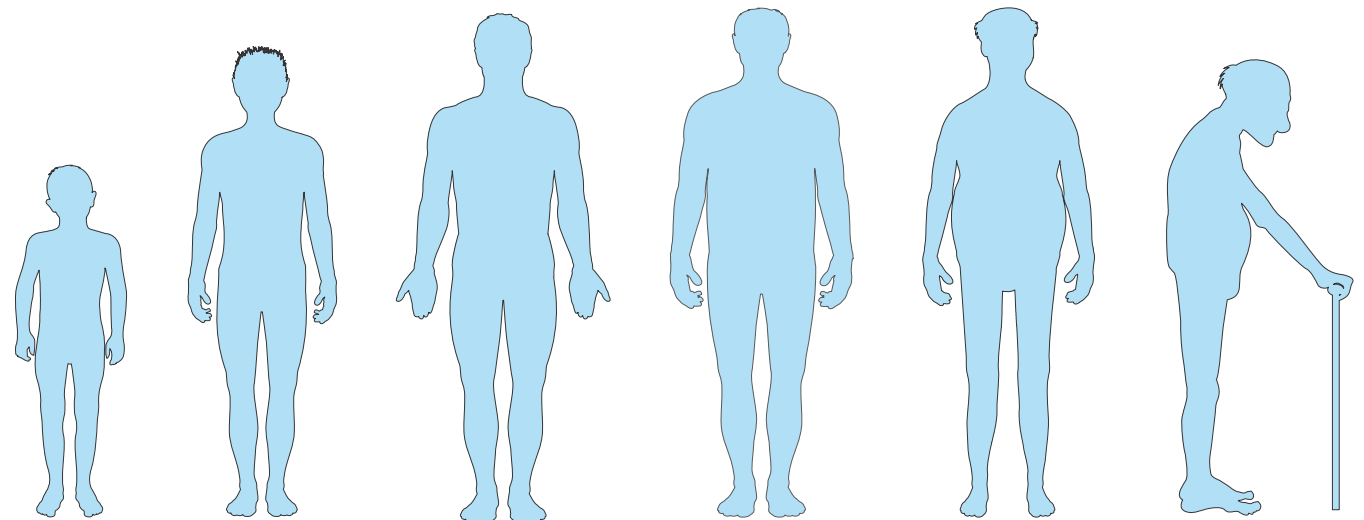
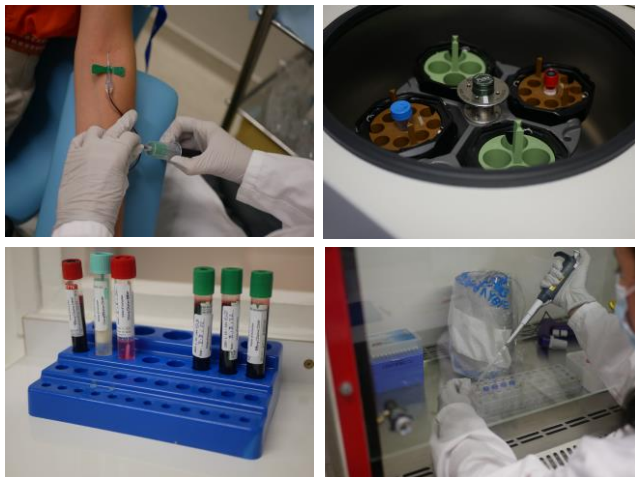
# The ICAReB-biobank entity

---

The **ICAReB-biobank (Integrated Collections for Adaptive Research in Biomedicine)** collects and offers various human biological resources from healthy volunteers and patients to the scientific community such as: blood and derivatives, saliva, stool, nasopharyngeal swabs, etc., for a total of more than 150,000 samples in stock.

The ICAReB-biobank supports clinical trials in close collaboration with the Medical Department, in particular the *Pôle Investigation et Recherche Clinique* (PIRC) and the Institut Pasteur Medical Center (CMIP).

In addition, this entity hosts the collections from closed research projects with a view to their reuse.

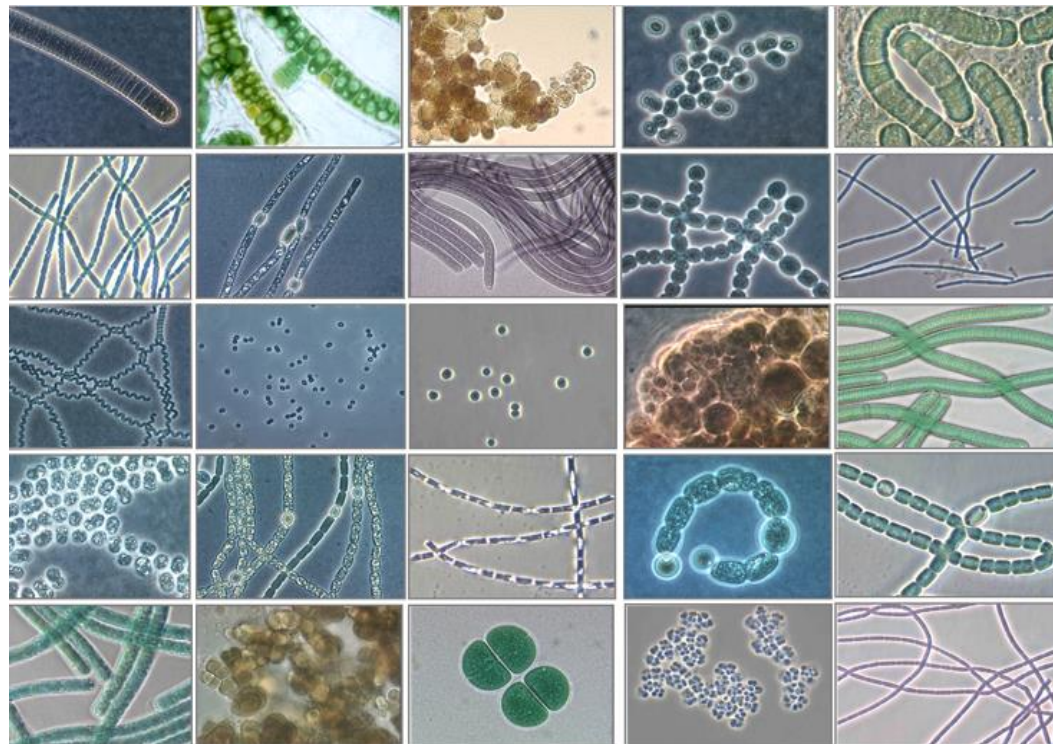




# The PCC entity

---

The **Pasteur Cultures of Cyanobacteria (PCC)** holds a collection of 750 pure strains of isolated cyanobacteria, which represents most of the morphological, physiological, and ecological diversity of this phylum.

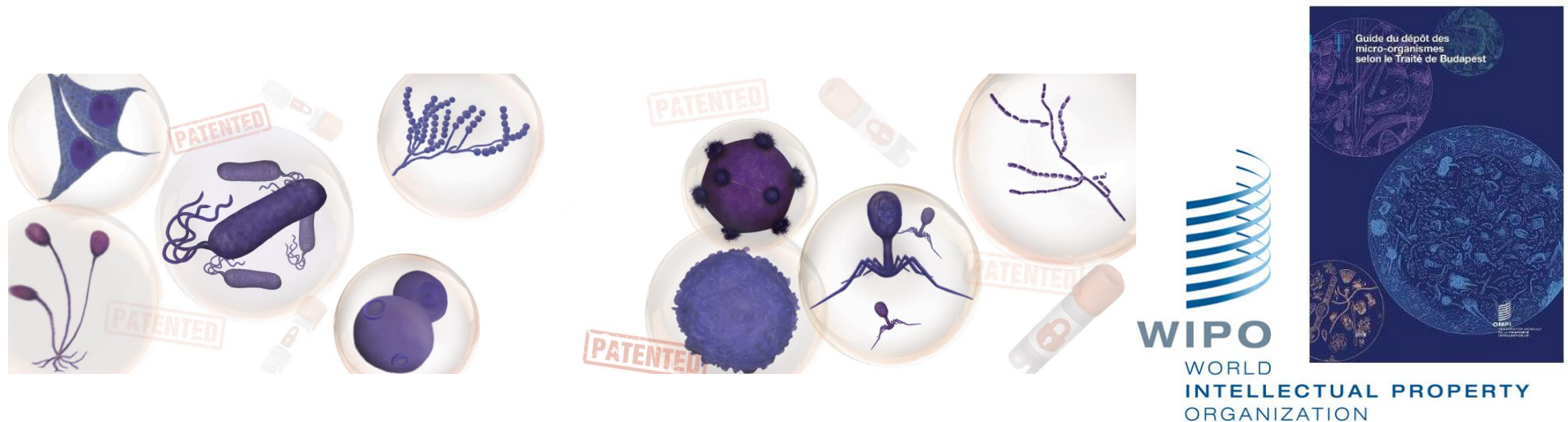


Morphological diversity of PCC strains

# The CNCM entity

The **National Collection of Microorganism Cultures (CNCM)** is an International Depository Authority (IDA) under the Budapest Treaty. It is a separate unit, ensuring the safeguarding of the integrity and controlled accessibility of microorganisms and cell lines, deposited for the purposes of patent proceedings. The CNCM is the only IDA in France and the second in Europe in terms of the number of deposits received since obtaining IDA status in 1984.

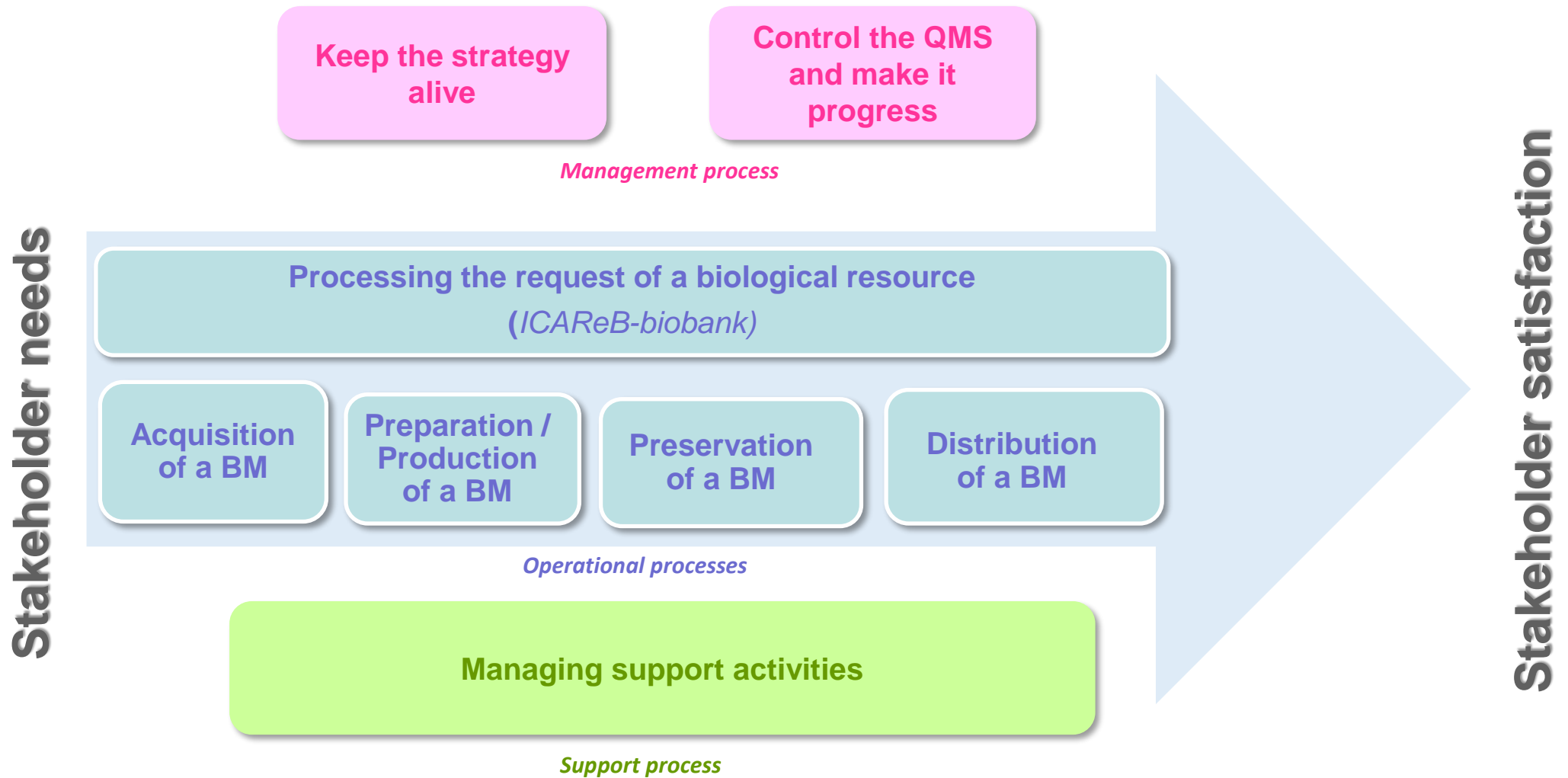
As a collection of microorganisms authorized for patent purposes, the CNCM receives deposits for the purposes of national and international patent procedures or for other purposes requiring high secrecy requirements.



***The CNCM is not part of the CRBIP certification scope***



# Process roadmap



*BM: Biological Material*

# The CRBIP's internal partners

| Department   | Role  |
|--|---|
| <b>General Department</b>  | IP Quality Policy and Strategic Direction   |
| <b>Medical Department</b>  | Development of medical research, strengthening of public health activities, organization of partnerships with hospitals and medical research structures, advice and evaluation of international medical and scientific affairs  |
| <b>Human Resources Department</b>  | Administration of personnel files, recruitment and mobility, implementation of training plans   |
| <b>Legal Department</b>  | Design and validation of MTA, validation of General Sales Conditions, legal formatting and finalization of contracts negotiated by DARRI, legal monitoring and application of legislative and regulatory texts on microbial collections (e.g., Nagoya, Budapest Treaty) and human collections (e.g., Jardé Law), other legal missions |
| <b>Financial Department</b>  | Budget management, management control, cost analysis, order entry, new customer creation, sales invoicing   |
| <b>Education Center</b>  | Management of teaching on biodiversity of microorganisms and biobanking   |
| <b>Technology Transfer and Industrial Partnership Department (DARRI)</b>           | Negotiation of the contractual conditions with the industrials, interlocutor of the IP patent deposits  |
| <b>Scientific Evaluation Department (DES)</b>                                      | Evaluation of scientific entities (CIP/PCC)   |
| <b>International Department - International Network of Institut Pasteur (RIIP)</b> | Collaboration dans le périmètre des entités du RIIP détenant des collections  |
| <b>Information Systems Department (DSI)</b>  | Design and management of software and other database management tools<br>Data backups<br>Management of interfaces between information systems   |

# The CRBIP's internal partners

| Department  | Role   |
|---|--|
| <b>Scientific Careers Department (DCS)</b>                  | Evaluation of scientific frameworks  |
| <b>General and Scientific Secretariat (SGS)</b>             | Management of the "Research" website<br>Implementation of decisions after evaluation of research entities  |
| <b>Communication and sponsorship department</b>             | Management of the "Public Health" website  |
| <b>Technical Resources and Environment Department (RTE)</b> | <p><u>Preparation Service</u>: Preparation of culture media, preparation and distribution of laboratory glassware and consumables</p> <p><u>Technical Services</u>: Maintenance, intervention and upkeep of equipment, "OCEASOFT" management, printing of informative material (brochures, posters, etc.) for communication</p> <p><u>Risk Prevention Department</u>: Training in the prevention of biological, chemical and other risks, assistance in the application of regulatory requirements and controls (GMOs, MOTs, etc.)</p> <p><u>Quality, Environment and Sustainable Development Department</u>: Support, advice and facilitation for the QMS, organization of audits, Webcampus tool administrator, management of general procedures, metrological services, cleaning services, training/awareness-raising</p> <p><u>Logistics and Security Department</u>: reception of shipments, collection and dispatch of products, mail management</p> |
| <b>Archives Services</b>                                    | Archiving of paper records, study documents, medical records   |
| <b>Technology Department (DT)</b>                           | Main affiliation of CRBIP, strategic collaboration in projects for the development of new technologies, support for projects requiring bioinformatics expertise (Hub C3BI - Bioinformatics and Biostatistics)  |
| <b>Grant Office Development Department</b>                  | Monitoring and support for responding to calls for proposals (national, European and international)  |

# Participation in networks and infrastructures

France

**Club 3C-R** (Network for Biological Resource)



**IBISA** (Infrastructures in Biology, Health and Agronomy)



**GIS CYANOBACTERIES**



Europe

**ECCO** (European Culture Collections' Organisation)



**MIRRI** (Microbial Resource Research Infrastructure)



International

**ESBB** (European, Middle-Eastern and African Society for Biopreservation and Biobanking)



**ISBER** (International Society for Biological and Environmental Biorepositories)



**WFCC** (World Federation for Culture Collections)

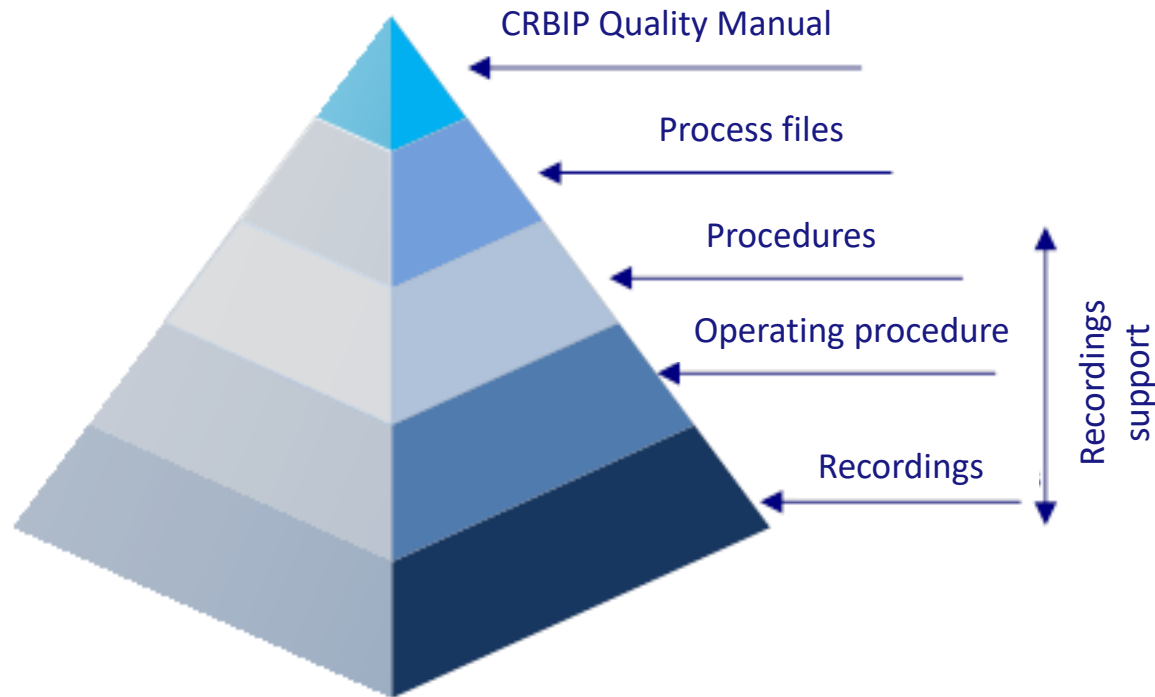


# Document organization

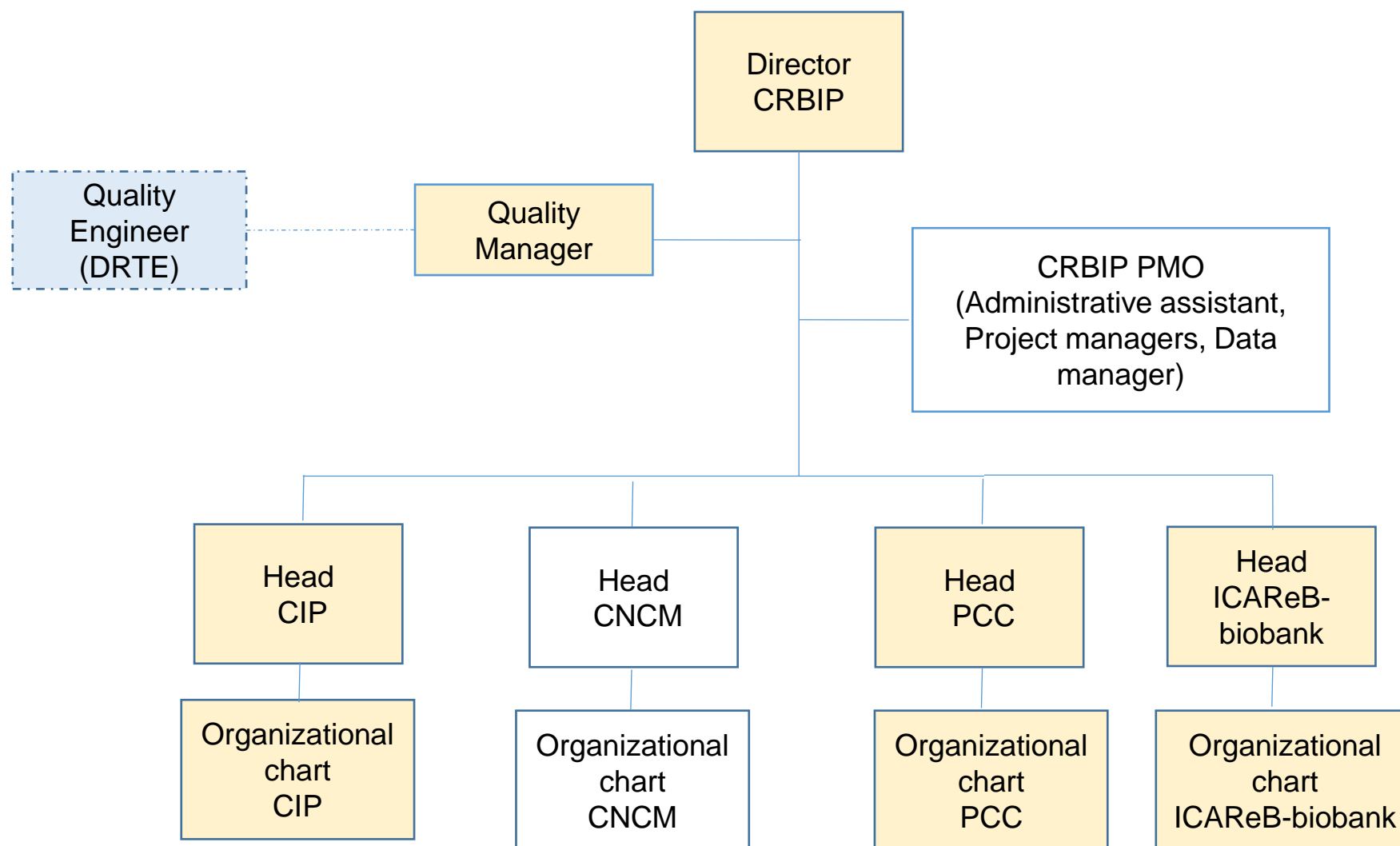
---

The general documentation of CRBIP is available in the Webcampus document management tool.

The records are available either in paper version or in computerized version on the shared network within the Institut Pasteur, Paris.



# The CRBIP functional organization chart

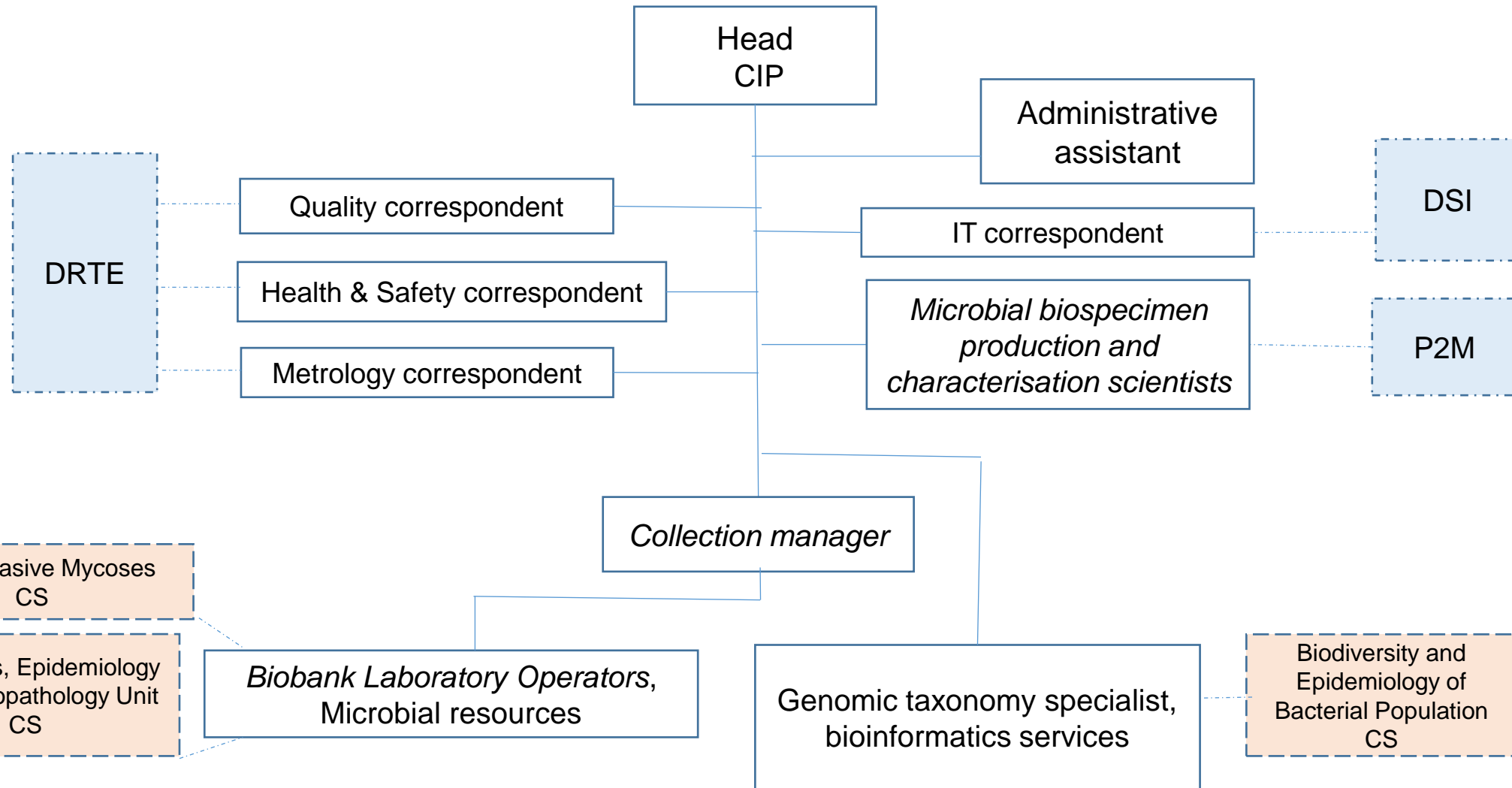


**Legend:**

- Hierarchical link
  - Functional link
  - Support Service
  - SMQ scope
- DRTE Technical Resources and Environment Direction



# The CIP functional organization chart

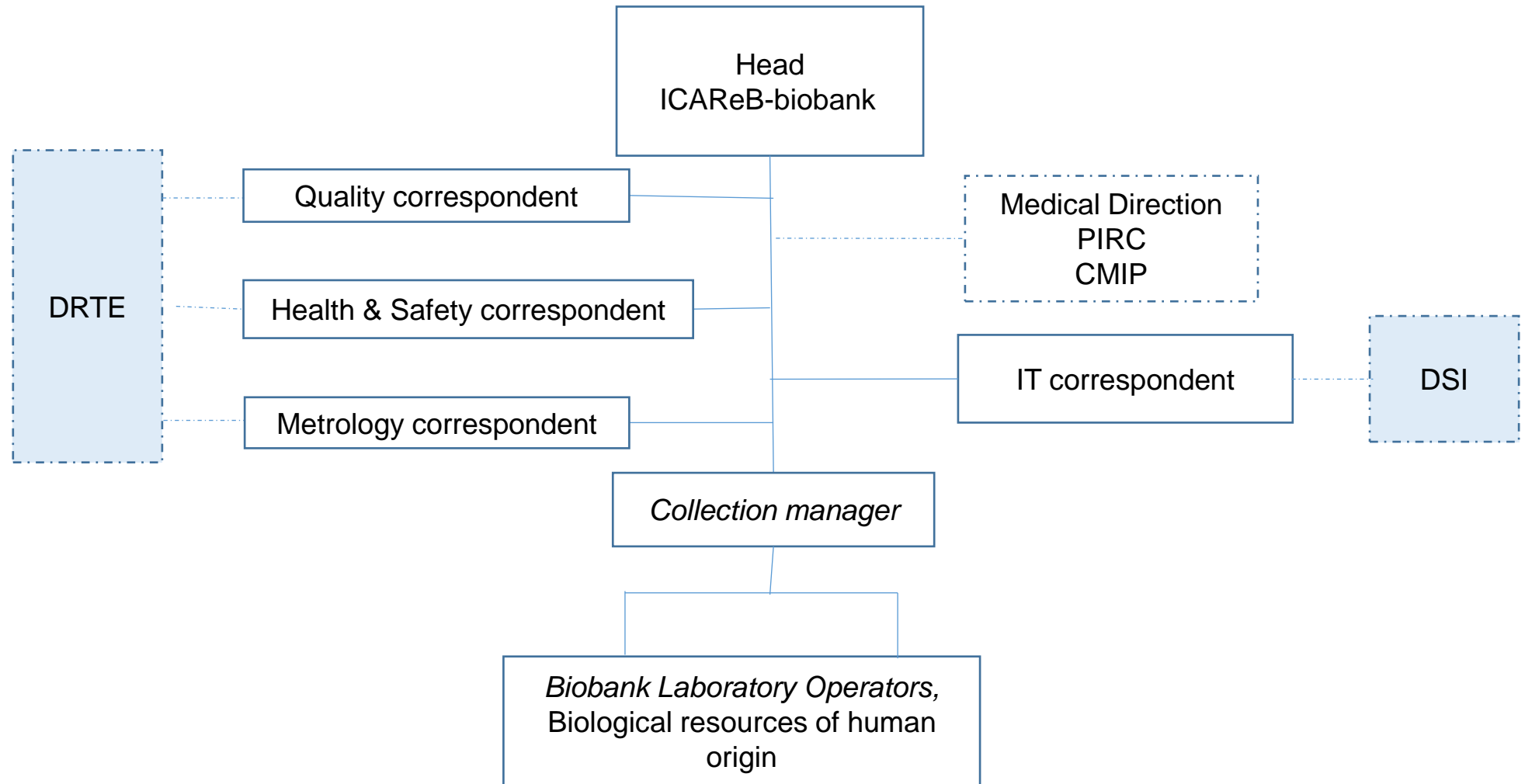


**Legend:**

- Hierarchical link
- Functional link
- Support service
- scientific coordinator (subject matter expert)

DRTE Technical Resources and Environment Direction  
 DSI Information Systems Direction  
 P2M Platform of Mutualized Microbiology

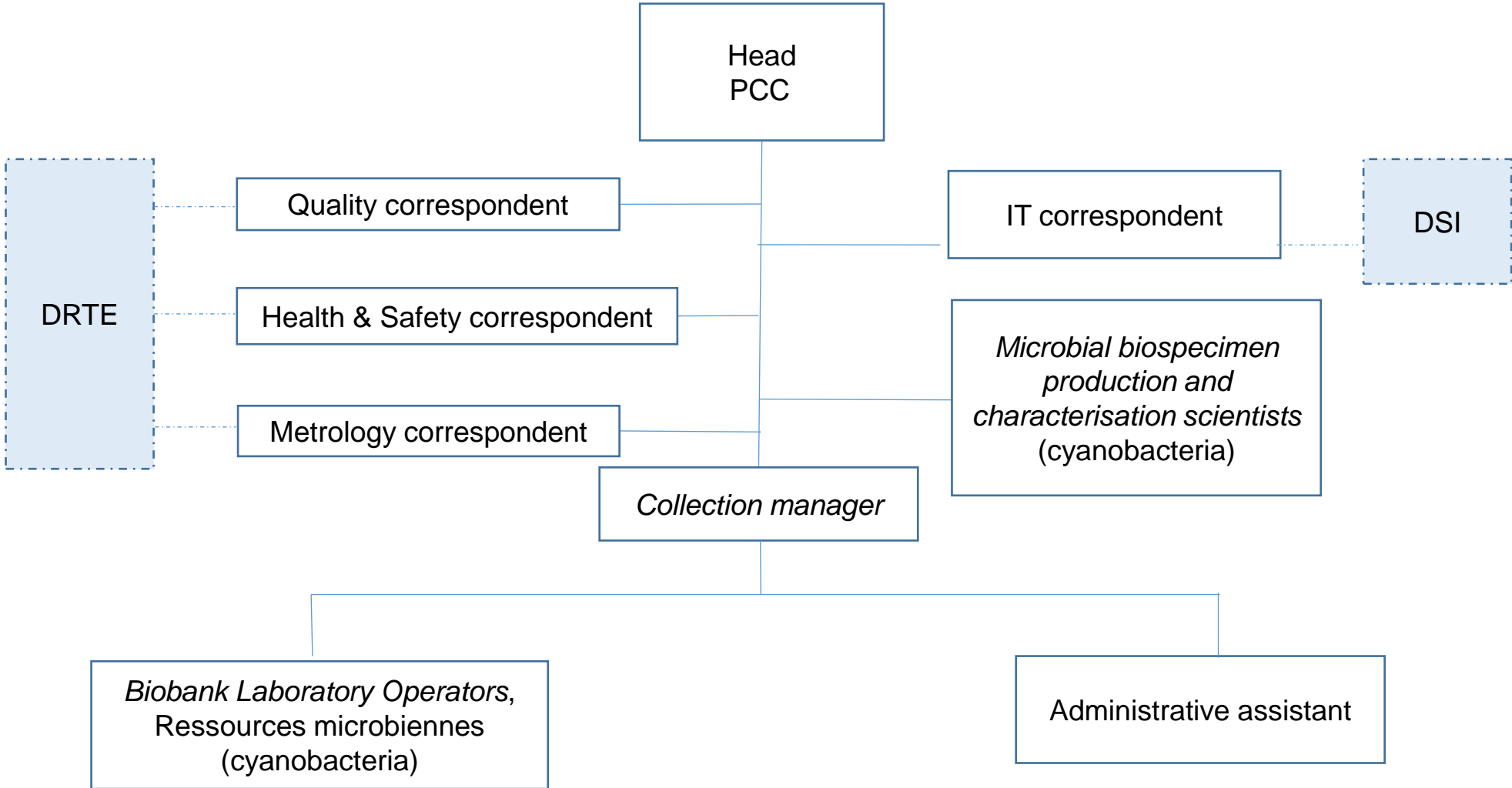
# The ICAReB-biobank functional organization chart



**Legend:**

- Hierarchical link
- Functional link
- Support service
- DRTE Technical Resources and Environment Direction
- DSI Information Systems Direction
- PIRC Investigation and Clinical Research Unit
- CMIP Institut Pasteur Medical Center

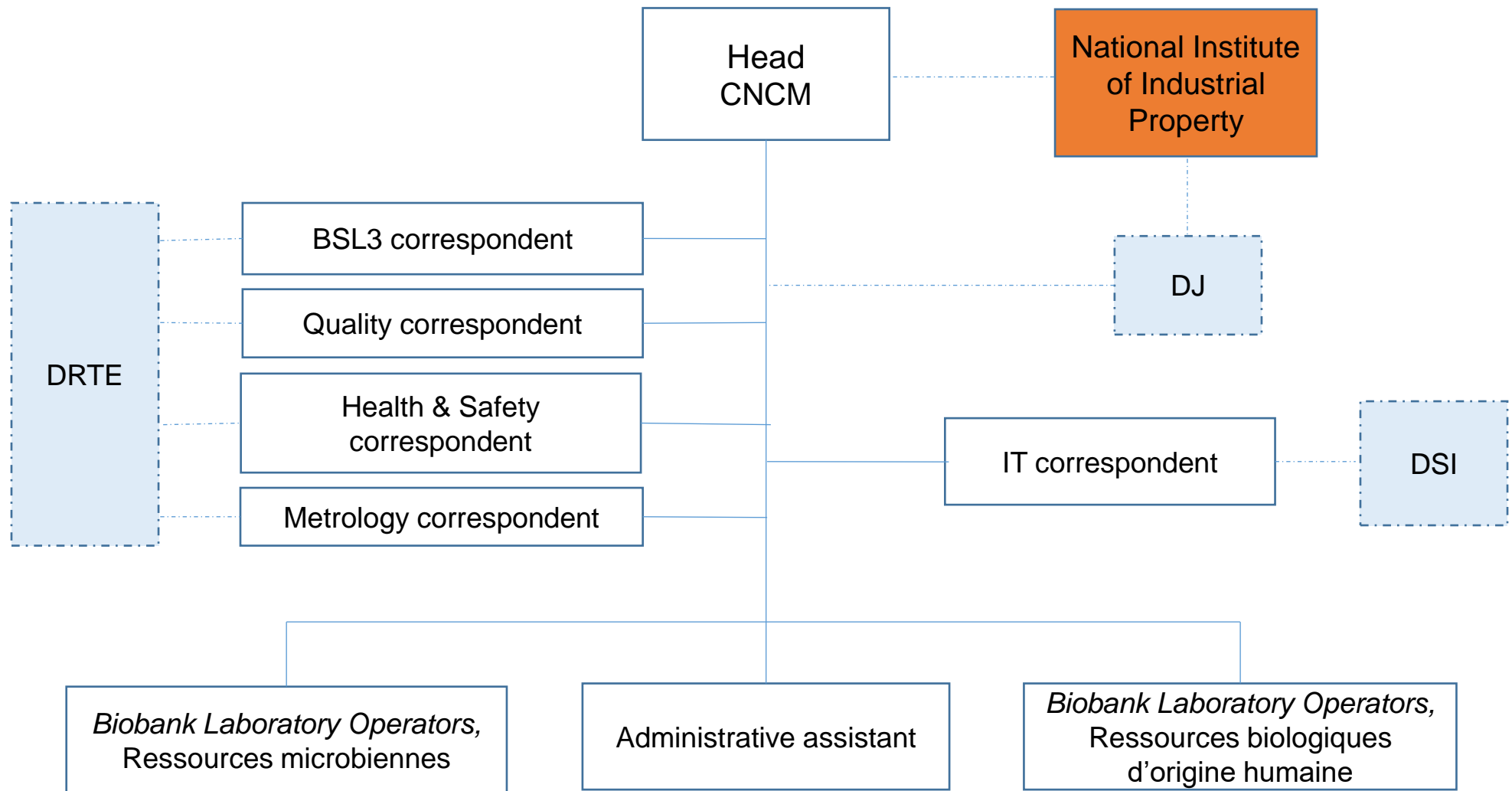
# The PCC functional organization chart



Legend:

- Hierarchical link
  - Functional link
  - Support service
- DRTE Technical Resources and Environment Department  
 DSI Information Systems Department

# The CNCM functional organization chart

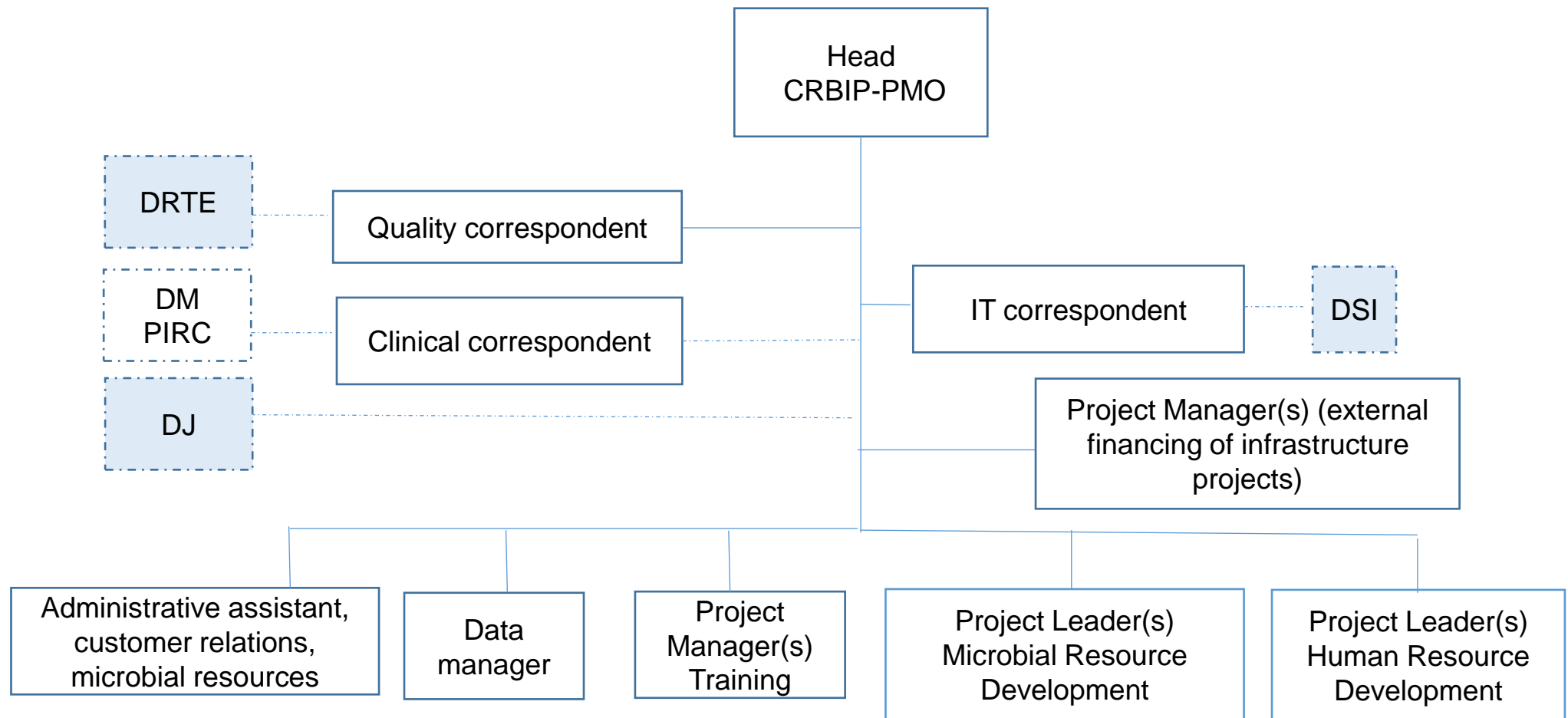


**Legend:**

- Hierarchical link
- Functional link
- Service support
- Co-tutorship

DRTE Technical Resources and Environment Direction  
 DSI Information Systems Direction  
 DJ Legal Direction

# The CRBIP-PMO functional organization chart



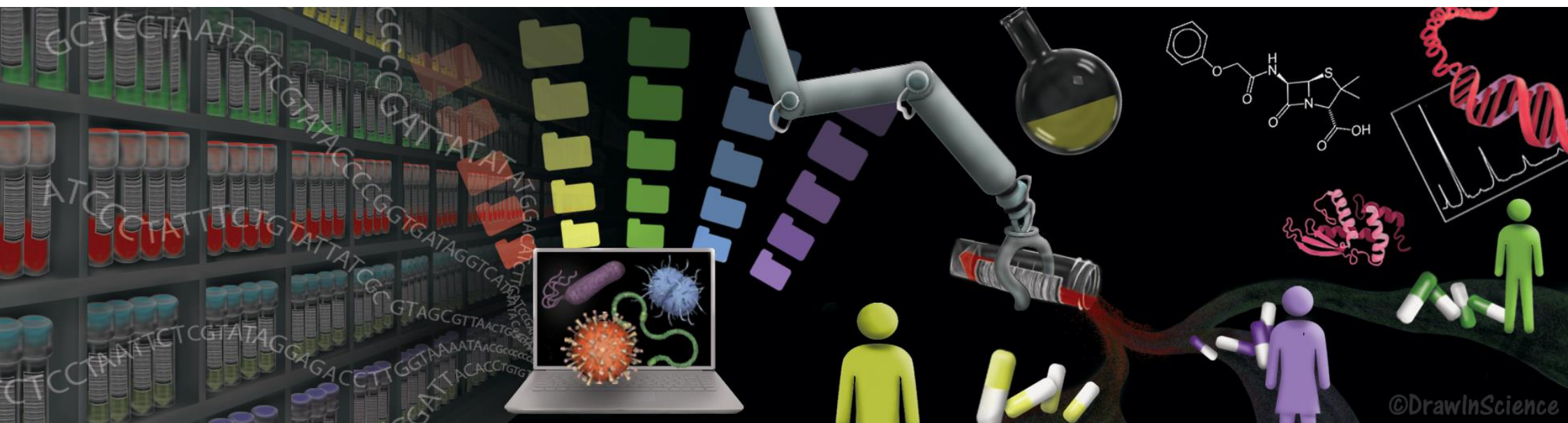
**Légendes:**

- Hierarchical link
- Functional link
- Support service

DRTE Technical Resources and Environment Direction

DSI Direction des Systèmes d'Information

DJ Legal Direction; GU, Guichet Unique; DRM, Medical Direction; DF, Financial Direction, PIRC Investigation and Clinical Research Unit



[crbip@pasteur.fr](mailto:crbip@pasteur.fr)

Institut Pasteur  
25-28 rue du docteur Roux  
75724 Paris Cedex 15