

ECELLFRANCE User Charter

Introduction

ECELLFRANCE is a national research infrastructure whose mission is the development of innovative cell therapy based on the use of mesenchymal stem cells (MSC). The infrastructure includes 12 platforms distributed on 7 sites:

- Preclinical (Clamart, Grenoble, Montpellier, Toulouse)
- ATMP MSC production (Clamart, Créteil, Besançon, Grenoble, Toulouse)
- Quality control/safety/potency (Toulouse)
- Immunomonitoring (Rennes, Montpellier)

These platforms are intended for use, both, by the ECELLFRANCE teams for internal programs, and by external teams, academics or industrials, to support the implementation of their project.

The purpose of this charter is to inform users on the procedure and conditions to access the platforms, and to establish the terms and conditions of use that the users undertake to respect.

Access terms and conditions

The external teams requesting support from the infrastructure platforms are subjected to assessment of their project.

Projects involving a single site of ECELLFRANCE are assessed by the scientific director of the site involved, whereas those involving several sites are assessed by the steering committee on the advice of the scientific committee, following the following procedure:

1. The applicant fills in the application form (uploaded from the website).
2. The application is assessed by the scientific committee using the criteria provided below.
3. Project acceptance or rejection is voted by the steering committee, and a report explaining the reasons of the decision is provided to the applicant.

The applicant may be called upon during the process to answer some of the points raised by the scientific or steering committees.

¹ A platform is the grouping, on the same site, of equipments and human means intended to provide high-level technological resources, for a defined service, to the users' community.

Projets evaluation criteria :

- **Adequacy between the project and ECELLFRANCE:** do the goals and purpose of the project lie within the ethical, regulatory, and scientific framework of the infrastructure?
- **Consistency and feasibility:** is the project built in a coherent and realistic way with respect to its objectives (applicant expertise, competition context, preliminary data, preclinical data...)?
- **ECELLFRANCE capacities to meet the project objectives:** does the infrastructure have the tools, expertise, and equipments required to meet the project needs? The platforms occupancy rate needs to be taken into account.

Once a project has been accepted, access to ECELLFRANCE platforms by external teams is achieved through service provision contracts or through research contract agreement.

Implementation and operation of a project

A service provision contract or a research contract agreement (depending on the case), shall be offered by ECELLFRANCE to the external team. Its purpose is to:

- define the terms and means for carrying out the project
- define the financial conditions to carry out the service provision or the research agreement
- organize the strategic, operational, and financial follow-up
- establish the intellectual property rules on the results
- establish the general terms and conditions for operating and use of the research result

Besides contract agreement, the implementation phase generally requires to draw up numerous documents (protocol, investigator's brochure, IMPD, CPP file, CRF, complementary funding application, ...) which requires efficient cooperation and information exchange between the external teams and ECELLFRANCE. Therefore, the external team **commits to be available and responsive**, in particular by responding to ECELLFRANCE's solicitations (information request, work meetings, ...) within reasonable time.

Lastly, the external team **commits to acknowledge « ECELLFRANCE research infrastructure » in all communications and publications** that include data produced by any of its platforms.