Quality &Animal Welfare

Describe the process involved in managing studies.

The process involved in managing studies start with a study proposal followed by a study design. All animal procedures are carried out in accordance to the guidelines of the European Community's Council Directive 2010/63/EU on animal protection and welfare. Moreover, all processes, including animal welfare and experimental procedures, are documented in our Quality Management System.

What qualification holds the staff involved in animal experiments of sponsored studies ?

All the staff members involved in the study hold the authorization to perform animal experimentation and have several years of experience in neurosciences, pharmacology, surgery, signal recording or processing. Half of our team holds a PhD, and all SynapCell experimenters are involved in a continuous training program certified by the French Ministry of Agriculture. Training programs could be either internal or external.

Can studies be conducted under GLP ?

All studies are performed following SynapCell local **Standard Operating Procedures (SOP)** and are inspired from the OCDE rule of **Good Laboratory Practices** [C(97)186/Final]. Even if preclinical efficacy studies are not required to be GLP compliant, SynapCell sets its own Quality Management System.

How does your company secure Sponsor's information ?

SynapCell IT security consists in protecting the company's computer systems from the theft or damage to its hardware, software or information, as well as from disruption or misdirection of the services provided.

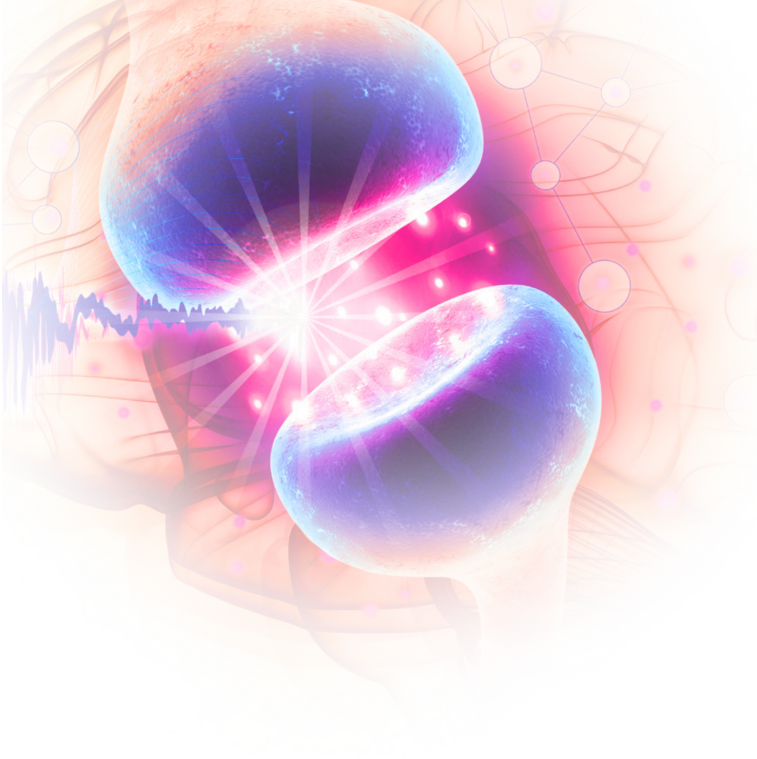
Security measures taken include controlling **physical access** to the hardware, as well as protecting against harm that may come via **network access, data and code injection.**

Therefore, Sponsor information is managed by 3 levels of security:

Physical security : there is a restricted access to the building for everyone, it needs a magnetic badge detained by SynapCell employee

Daily Backup : workstations are backed up to server once a day and additional backup run every night through Internet on a dedicated remote server

Access-Information : Incident or failure will be automatically fixed through a SPARE drive automatic take over system.
In addition, all team members involved with the Sponsor's project, are committed to full confidentiality.



SYNAPCELL

Your Drug Efficacy.
Now Revealed.

FAQ

Organization

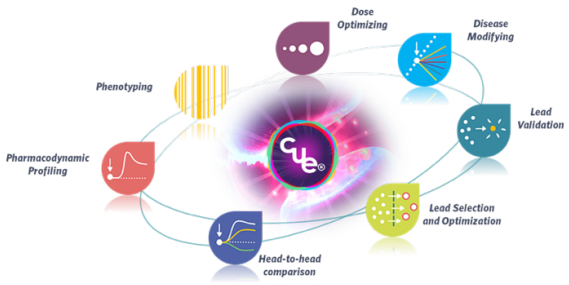
About SynapCell

SynapCell is a **CNS-expert biotechnology** company with more than **12 years of experience**, whose mission is to support drug developers in discovering new treatments for CNS disorders. We identify and qualify **the therapeutic potential** of our clients' lead candidates on Epileptic, Cognitive, Movement and Neurodegenerative disorders. In other words, **SynapCell tests for you the efficacy of your compound.**

At SynapCell, we do care about environmental footprint. From December 2017, we have entered our brand-new energy-efficient facilities **at the heart of the French Silicon Valley**, close to Grenoble.

Describe how you evaluate a Sponsor drug effect

Since 2005 we have been developing **Cue®**, our drug discovery solution that can **predict in-human efficacy** of a lead candidate, at the preclinical step. EEG-based and **patient inspired**, Cue® is the smart combination of a team with specific skillsets in Neuroscience, translational rodent models, high-end recording techniques and proprietary signal processing. SynapCell's technology can measure specific oscillatory activities from **any brain structure**. Known to be altered in CNS disorders and highly conserved across species, these **EEG biomarkers** are used to determine the effect of a given molecule on brain function.



To your specific question, Cue® offers a series of **pharmacodynamic assays** for lead selection (screening of small libraries of compounds), lead validation (dose-response effect, pharmacokinetics), disease modifying potential, antiepileptogenic effect, model phenotyping, de-risking (pro-epileptic effect), dose optimizing and much more. Cue® can also **read any of your past EEG** recordings to deliver precise outcomes and help you **make decisions**.

Please describe your facilities

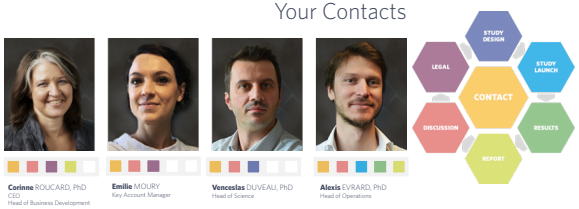
We are a fully **integrated company**, with our own animal and research facilities. As a French organization, the animal facility is certified by the French Ministry of Research and the Veterinarian Service. As of 2017, the facility covers as much as 3600 square feet, and has a capacity of over 300 animals. Access to the platform is restricted to authorized personal exclusively with high-level of security. See Quality &Animal Welfare section for more details.

We do apply the **Three R's sustainability rule** (Replacement, Reduction, Refinement) in the way we conduct our activities. In addition, all protocols are submitted to and **approved by the Ethic Committee**. To support both internal and external R&D programs for our clients, we have developed three **cutting-edge platforms in-house** for Neurosurgery, EEG/ERP recording and advanced Signal analysis. Everything is therefore performed internally for optimum project efficiency, tracking, quality management and cost optimization.

Who is the primary contact in the relationship with the Sponsor ?

Keeping close contact with the Sponsor is key for both parties **to get aligned on all milestones and deliverables** of the study. This is done for each client from project initiation to completion, at every individual step. Your main contacts will be with our Business Development team (Key Account Manager and Head of Bus. Dev.) for commercial and legal steps, our Head of Science for protocol and study design and with the Head of Operations for project coordination and study report.

Project Management
Your Contacts



Project Management

What is the timeline from contract execution to initialization of a study ?

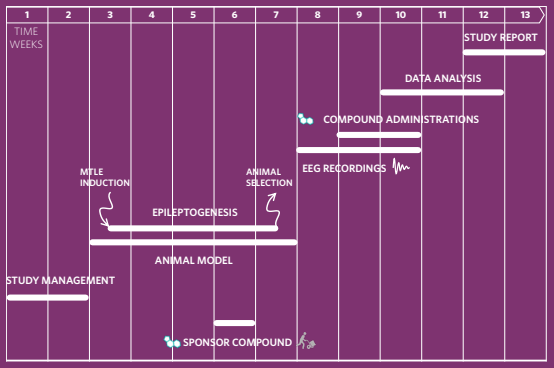
Once commercial and legal steps are completed, and agreement has been made between SynapCell and the Sponsor on the study details, the project is ready for launch. Depending on the nature of the study, this step can take **2 to 3 weeks on average if a planning slot is available.**

What is your average time-to-result ?

On average, **between 3 to 6 weeks** from study launch for first data and from **11 to 15 weeks** for the final report if Sponsor compound is received on schedule. For example, a full dose-response assessment of an anti-epileptic compound on the SynapCell MTLE mouse takes 7 weeks to generate the model (Epileptogenesis phase) and 4 to 5 additional weeks to generate the results.

What is the timeline of your communication with the Sponsor ?

We are committed to providing the Sponsor with **proactive feedback** all along the study course. At each important milestone of a study, a meeting with the Sponsor is arranged, to provide an update on the most recent results.



Can you perform Tox/Safety Studies?

We do not conduct Toxicity nor Safety Studies. We are focusing our offer on **preclinical efficacy studies** that are performed **exclusively in vivo** on **freely-moving** animal models. Nonetheless, we pay a particular attention to animal welfare all along the study course. In the event of potential toxic effect observed, we immediately warn the Sponsor for action.

For more information, please contact the team at **hello@synapcell.fr**
The SynapCell team.