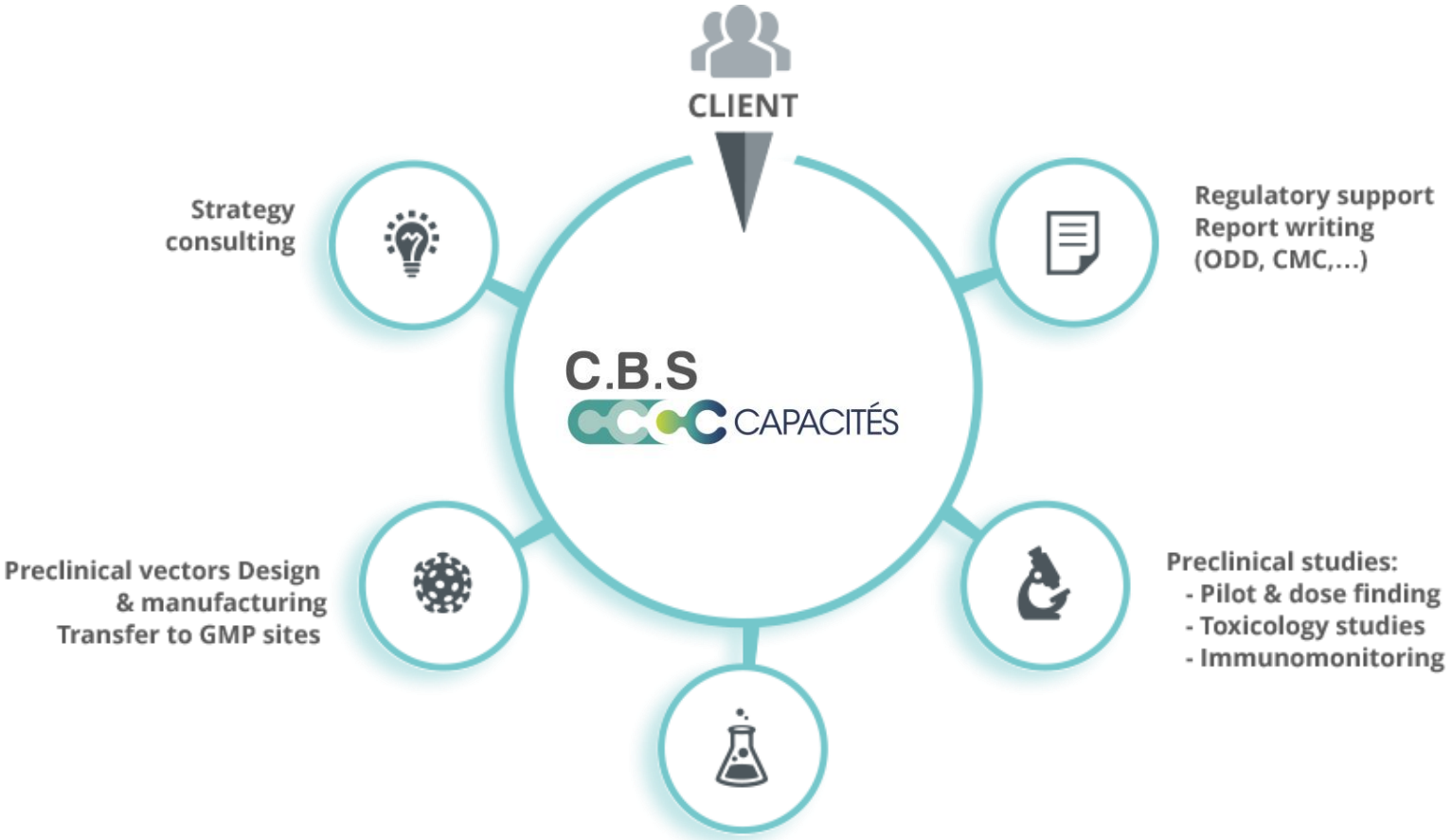
C.B.S CAPACITÉS

Capacités Biotherapeutics Solutions (C.B.S) is a newly created business unit of CAPACITÉS LLC, an affiliate company of the University of Nantes (France).

By gathering experts and core facilities, C.B.S proposes to biotechnology, pharmaceutical companies and academic teams, a one-stop shop at all stages of their gene therapy preclinical developments.



CAPACITÉS UNIVERSITÉ DE NANTES

OUR MISSION

C.B.S is assisting biotech and academic entities to implement and de-risk preclinical development for their gene therapy programs.

C.B.S provides access to the scientific expertise of the gene therapy institute and core facilities of Nantes.

OUR EXPERTISE

C.B.S provides assistance at all steps of gene therapy preclinical developments

OUR SERVICES

CAPACITÉS UNIVERSITÉ DE NANTES

OUR CORE FACILITIES

Translational Vector Core

Production	• Production of research grade AAV and adenoviral vectors • In vitro/in vivo assays & proof of concept in small/large animal models • 400 lots/year
R&D	• High yield custom made processes for the production of AAV vectors • Analytical methods: potency, purity, identity • Transfer of GMP compatible manufacturing processes for viral vectors

Gene Therapy Immunology Core

G.T.I	• Large expertise in monitoring of host immunity in preclinical and clinical gene therapy protocols • Participation in preclinical studies performed in rodent, canine and non-human primate models • Monitoring of humoral & cellular immunity against viral vectors (AAV, adenoviral) and transgene products • Large panel of validated assays including cell isolation, cell phenotyping, ELISA, ELISpot, Western Blot, cytokine detection… • GCLP guidelines for studies with regulatory requirements (clinical trials and Tox studies)

OUR CORE FACILITIES

Preclinical Analytics Core

P.A.C

- Evaluation of in vitro & in vivo functionality of therapeutic reagents, including gene therapy products
- Evaluation of gene therapy product biodistribution & shedding by qPCR following in vivo administration
- Evaluation of gene therapy product expression profile by RT-qPCR & Western-Blot following in vivo administration
- High expertise in preclinical studies performed in rodent, canine and non-human primate models, including toxicological gene therapy studies

Pathological Core

APEX

- Expertise in Pathology – 15 years of practice in analyzing genetically-modified tissues
- In a large spectrum of animal species
- Synergy between expertise in morphology, pathology, fluorescence imaging & molecular biology on slides
- Integrated offer for tissue Phenotyping - Tissue sampling & trimming - Topographic staining - Immunostaining and histoenzymology - in situ hybridization - Fluorescence bio-imaging - Histomorphometry
- 2 veterinary pathologists (ECVP diplomates) including a neuropathologist

OUR CORE FACILITIES

Animal Core Facility

Animal Core Facility

- 1600m2 (+350m2 office)
- Animal models housing and keeping including breeding of rare colonies
- Preclinical studies for gene & cell therapy and pharmacologic products
- Large expertise in rare animal models of genetic diseases
- Synergy and complementarity with external medical specialists

CAPACITÉS Biotherapeutics Solutions (CBS)

Your needs	Our services	Our experts
Making strategic decisions	20 years of expertise in gene therapy	Experts in gene therapy
Selecting vector technology	AAV production Baculovirus/Transfection	Experts in preclinial & clinical immunomonitoring
Reviewing your preclinical data	Proof-of-concept, Product-design, Process development, Analytics	EMA board certified pathologist with more than 10 years experience
Designing your preclinical data	GMO risk assessment, ODD, IMPD-CTD	Experts in regulatory requirements
Accesing your regulatory documents	Dose-finding, Toxicology & biodistribution studies in vivo models	Experts in IND submissions

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