DRUG DEVELOPMENT UNIT

DDUNAV

Universidad de Navarra | SERVICIO DE GESTIÓN DE LA INVESTIGACIÓN

DDUNAV: Drug Development Unit

DRUG DISCOVERY → **PRECLINICAL DEVELOPMENT** → **CLINICAL DEVELOPMENT**

PHARMA / BIOTECH / NUTRI

DRUG DISCOVERY

Competitive Projects

National (Public Funds)

EU: IMI

UNAV Funds

UNAV Centers

CIN CIMA

Faculties

Pharmacy Sciences
Chemistry Biochemistry

PRECLINICAL DEVELOPMENT

Toxicology Unit

GLP standards

PKPD Modeling Unit

Animal Facilities

Quality Assurance Unit UGC

Radiolabeling Unit

CLINICAL DEVELOPMENT

Phase II-III Facilities

Clínica Universidad de Navarra

Phase IV Facilities

PostAutorization

Other Capabilities

Cell Therapy Unit / GMP

RadioLabeling Unit PET-GMP Laboratory

CIMA Lab Diagnostics

Preclinical Development: Toxicology Unit

Capabilities

- **General Toxicology**
  - Single dose studies
  - Repeated dose studies
  - Maximum tolerated dose studies
- **Specific Toxicology**
  - Local tolerance studies
  - Skin & Eye irritation/corrosion studies
  - Phototoxicity studies
  - Immunogenicity studies
  - Mutagenicity genotoxicity
    - ✓ Ames Test
    - ✓ *In vitro* and *in vivo* Micronucleus Test
    - ✓ *In vitro* and *in vivo* Comet Assay
- **Pharmacokinetic/ Toxicokinetic Studies & Biodistribution Studies**
- **Development of Animal Model Disease**
  - Oncology studies: breast cancer, melanoma, colon cancer, etc.
- **Efficacy Studies: *in vitro*/*in vivo* models**
- **Cytotoxicity Assays**
- **Biocompatibility studies of medical devices**

Experimental Models

Rat	Rabbit
Hamster	Macaque
Mouse	Others

Administration Routes

Oral	Dermal	Intramuscular
Subcutaneous	Rectal	Ocular
Intraperitoneal	Intravenous	Intravitreous
Vaginal	Other…*	

**Other complex administration routes in collaboration with CUN and CIMA researchers*

GLP Certification

Preclinical Development: Pharmacometrics / PKPD Modelling

Capabilities

- ***In vitro/in vivo* correlation:** predicting *in vivo* pharmacokinetic based on early data
- **PBPK Models:** early prediction of human pharmacokinetics
- **PK/PD Modeling:** link between drug concentration and bio- and/or surrogate makers
- **PK/PD population analysis:** models to describe the clinical outcome with clinical data
- **Drug Development Optimization:** statistical considerations and *in silico* simulations of the optimal scenario for future experiments/studies
- **Personalized medicine:** choosing the right drug and dose for each patient

Development mechanistic models ***"IN SILICO".***

Describing and predicting the time-course of disease progression and drug action at every step during the development of a new drug

Participation in:

Innovative Medicines Initiative

Drug Disease Model Resources ddmore

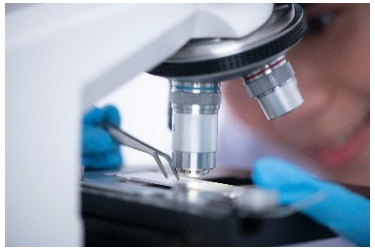


Preclinical Development: Microbiology Studies

Capabilities

- ***Studies on bactericidal and fungicidal efficacy*** (determination of MIC and MBC, antibiograms)
- **Preservative efficacy studies**
- **Validation of microbiological control methods** in pharmaceutical products
- **Microbiological testing of pharmaceutical products** (stability studies)
- **Validation of culture media productivity** used in microbiological control of pharmaceutical
- **Microbiological control** of water for injectable preparations
- **Sterility testing** of pharmaceutical products

The laboratory operates under a quality system in compliance with the ISO 17025 standard and Good Laboratory Practice (GLP) certification for the performance of microbiological studies on antibiotic efficacy, fungicidal efficacy, preservative effectiveness, and stability studies.



Preclinical Development: Animal Facilities

Universidad de Navarra, User Center ES/3120100000132. Authorized center for the housing of rodents (mainly rats and mice), rabbits, non-human primates (*Macaca fascicularis*) and farm animals (pigs and sheep)

Maximum capacities (according to Directive 2010/63/EU)

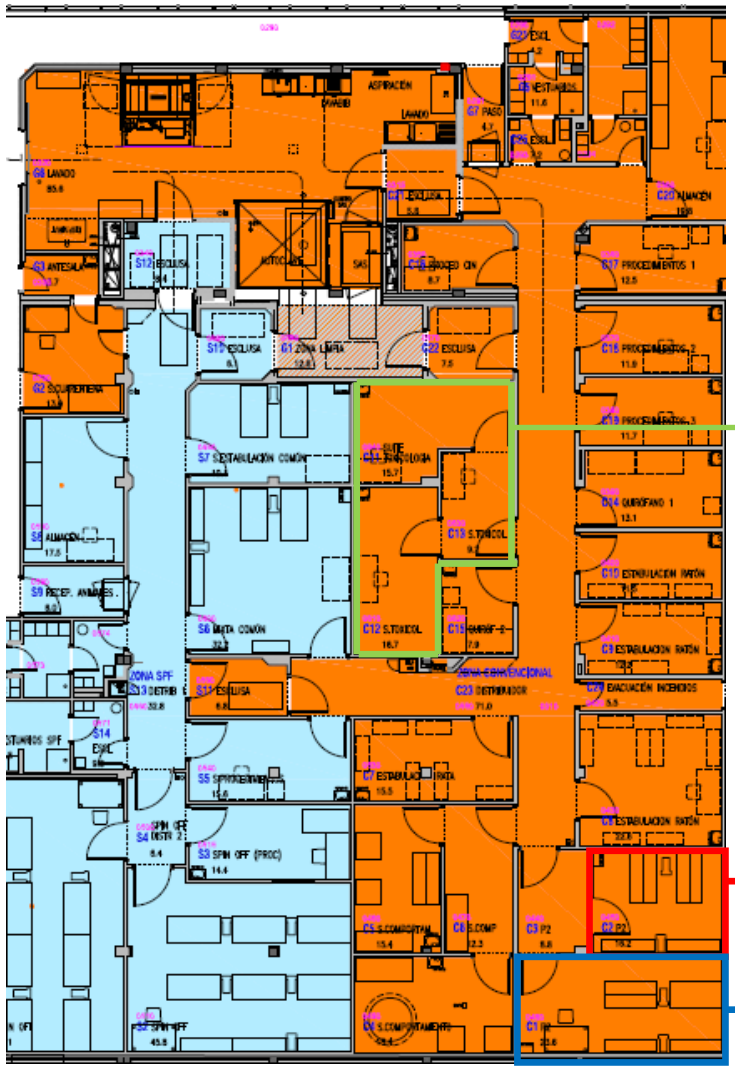
- Rat/mouse → 10.000
- Rabbit (< 3 Kg) → Up to 75
- NHP, Macaques (< 3 years) → Up to 200
- Farm animals:
  - Pigs (< 100 Kg) → 40 per room*
  - Sheeps (< 35 Kg) → 40 per room*
- 4 rooms available for housing these species

CIFA

Edificio de Experimentación

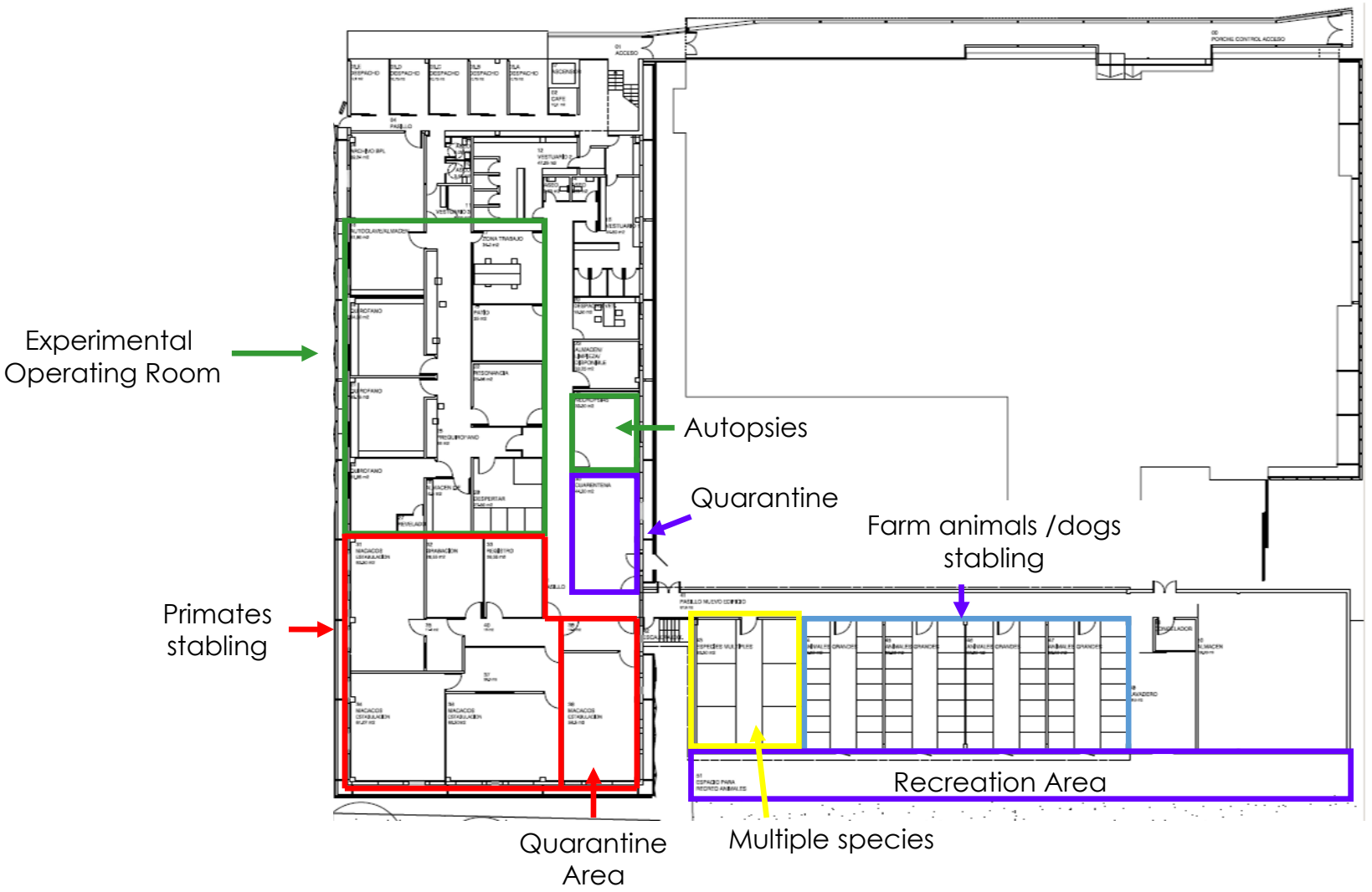
Preclinical Development: Animal Facilities

CIFA – roents stabling (500 m²)



Preclinical Development: Animal Facilities

Edificio de Experimentación – big animals stabling (2000 m²)



Preclinical Development: Experimental Operating Room

Facilities

Facilities authorized by the Government of Navarra as a user center, with the following distribution:

- **Pre-operating area** (66 m^2)
- **3 multipurpose operating rooms** (35 m^2 each)
- **Sterilization and storage room** (32 m^2)
- **Multipurpose working room** (34 m^2)
- **2 recovery rooms with monitoring**
- **Equipment storage area** (11 m^2)

Equipment

- **Surgical Equipment**
  - ✓ 2 Laparoscopy towers
  - ✓ 2 Interventional radiology systems
  - ✓ 1 Cardiac mapping navigation system (NOGA)
- **Anesthesia & Monitoring**
  - ✓ 5 Anesthesia stations
  - ✓ 1 Vascular blood flow monitoring system
- **Diagnostic Imaging**
  - ✓ 2 Diagnostic ultrasound systems

Preclinical Development: Experimental Operating Room

Capabilities

- **Experimental disease models** – large and small animals
- **Surgical procedures** – conventional and minimally invasive (laparoscopy, endoscopy, interventional radiology and cardiology)
- **Surgical support services**:
  - ✓ Anesthesia and monitoring
  - ✓ Postoperative care and sample collection
  - ✓ Euthanasia, necropsy and tissue collection
- **Technical-veterinary support and advice** in all procedures involving animals in the Experimental Surgery Area
  - ✓ Animal welfare guidance
  - ✓ Current legislation
  - ✓ Selection of appropriate animal models
  - ✓ Training in basic handling and surgical techniques
- **Diagnostic evaluation** – anatomical and functional assessment using non-invasive techniques
- **Functional, efficacy & safety evaluation** of medical devices, surgical devices and biomaterials

Accredited Staff

- **1 veterinarian and 1 nurse,** officially accredited for:
  - ✓ Function B – animal euthanasia
  - ✓ Function C – carrying out procedures
- **1 veterinarian**, officially accredited for:
  - ✓ Function B – animal eutanasia
  - ✓ Function C – carrying out procedures
  - ✓ Function D – designing projects and procedures
  - ✓ Function E – taking responsability for the on-site supervision of animal welfare and care
  - ✓ Function F – performing the duties of the designated veterinarian
  - ✓ Also serving as the Universidad de Navarra Welfare Advisor

Clinical Development: Clinical Trials

1 SITE 2 LOCATIONS MODEL:

- Pamplona
- Madrid

Phase II

Limited num. of patients

Preliminary data of safety / benefit of therapy

Phase III

Increase of patients

Safety and Efficacy Studies

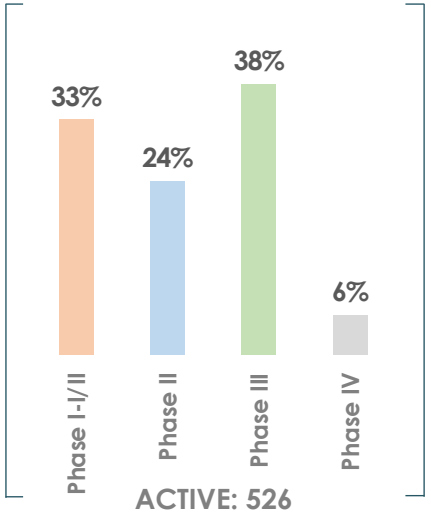
Phase IV

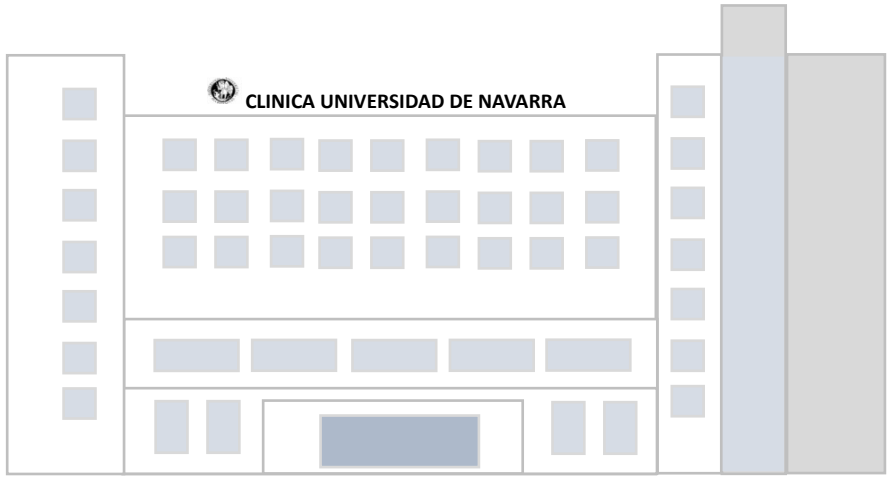
Product on the market

Long-term effects

27 Medical Departments of CUN

Clinical Trials Data





Main Areas of Clinical Trials

- Oncology
- Cardiology
- Neurology
- Haematology
- Ophthalmology
- Hepatology
- Dermatology
- OTL

Multidisciplinary environment

- ✓ Over 150 preclinical toxicology studies under GMP conditions

Multidisciplinary Collaboration
Work with clinical professionals from CUN and research teams from CIMA

Innovation & Infrastructure
Access to state-of-the-art platforms and technologies

Complex Administration Routes
Intrahepatic, intratumoral, intracisternal, etc.

CIMALabs
Advanced biodistribution analysis

RadioLabeling Unit PET-GMP Laboratory
Advanced biodistribution analysis

Universidad de Navarra

Clínica Universidad de Navarra

Cima Universidad de Navarra

Advanced Animal Models
Use of cutting-edge *in vivo* models

Complex Administration Routes
Intrahepatic, intratumoral, intracisternal, etc.

Added Value of DDUNAV

One-Stop-Shop

One place to develope your project

Flexibility

Flexible structure to adapt according to companies' needs

Management

Each Project is managed by a scientific responsible and a manager

Scientific Excellence

Each Project is designed to the highest scientific standards

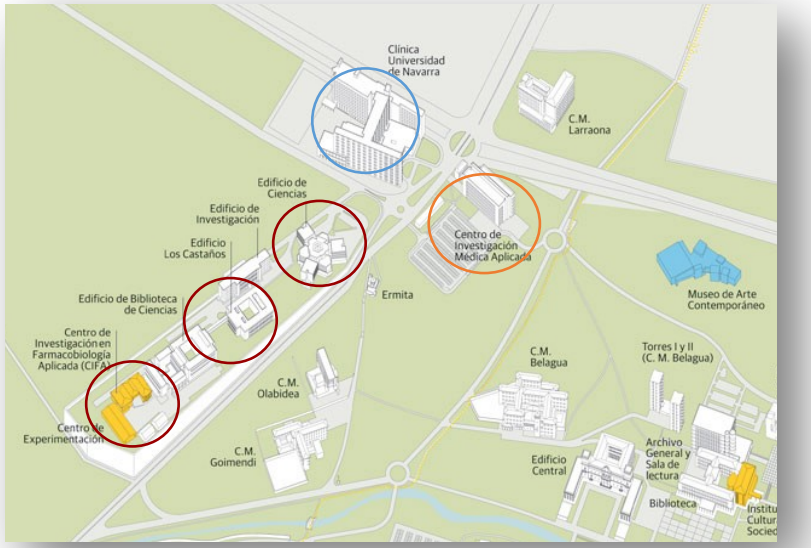
Drug Development

Experience in products from preclinical stage to Phase II approval

Team

Multidisciplinary teams involved in each project

BIOTECH ENVIROMENT



DDUNAV Unit

Toxicology

PKPD Modeling

Animal Facilities

UGC

CUN

Phase II -III - IV

Cell Therapy

Radiolabeling

CIMALab Diagnostic

CIMA

Platforms and technologies

Added Value of DDUNAV

WHY COLLABORATE WITH US?

1. Extensive experience in complex preclinical studies
2. GLP-certified since 2012 (second center in Spain to achieve certification; conducting studies since 1986)
3. Academic and innovation-driven environment fostering synergies and access to a vibrant biomedical campus and shared resources
4. Strong commitment to securing competitive funding and collaborative research opportunities
5. Agile and efficient project management

UNIVERSIDAD DE NAVARRA

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