



PHARMACEUTICAL CONTRACT DEVELOPMENT  
& MANUFACTURING ORGANIZATION (CDMO)

# COMPREHENSIVE MANAGEMENT OF PHARMACEUTICAL DEVELOPMENT PROJECTS





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TECNALIA, YOUR **BEST CDMO PARTNER** FOR DRUG DEVELOPMENT



TECNALIA is a full-service **Contract Development, Manufacturing Organization (CDMO)** that provides high quality services under a strong quality system, with over two decades serving the pharmaceutical industry.

AS A KEY FIGURE IN **CDMO**, TECNALIA IS PRESENT ON THE FOLLOWING MARKETS:



HUMAN MEDICINES



MEDICAL DEVICES



FOOD SUPPLEMENTS



COSMETICS



VETERINARY MEDICINES



**TECNALIA provides a broad spectrum of pharmaceutical outsourcing services** such as; formulation and analytical development, scale up & pilot batch manufacturing, quality control & batch release, stability studies, pharmacogenetics, phase I to IV clinical trials and contract manufacturing.

**TECNALIA CAN GUIDE YOU THROUGH YOUR ENTIRE PROJECT OR STEP AT ANY POINT YOU NEED:**



**ADDED VALUE**

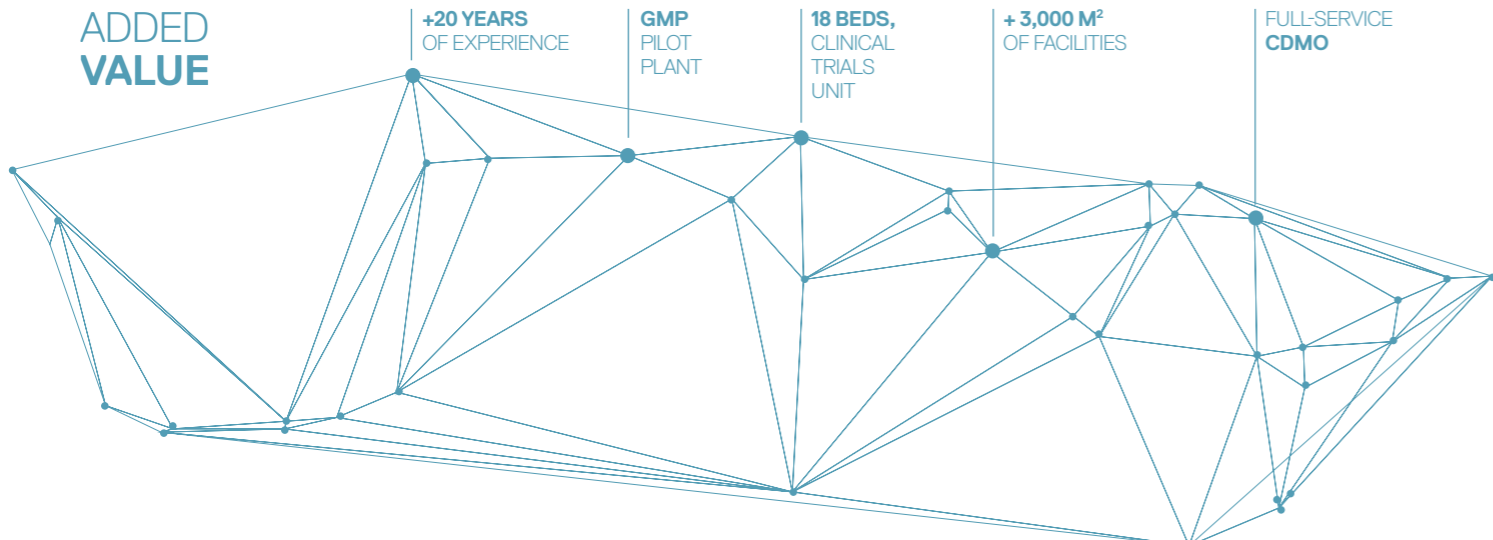
+20 YEARS OF EXPERIENCE

GMP PILOT PLANT

18 BEDS, CLINICAL TRIALS UNIT

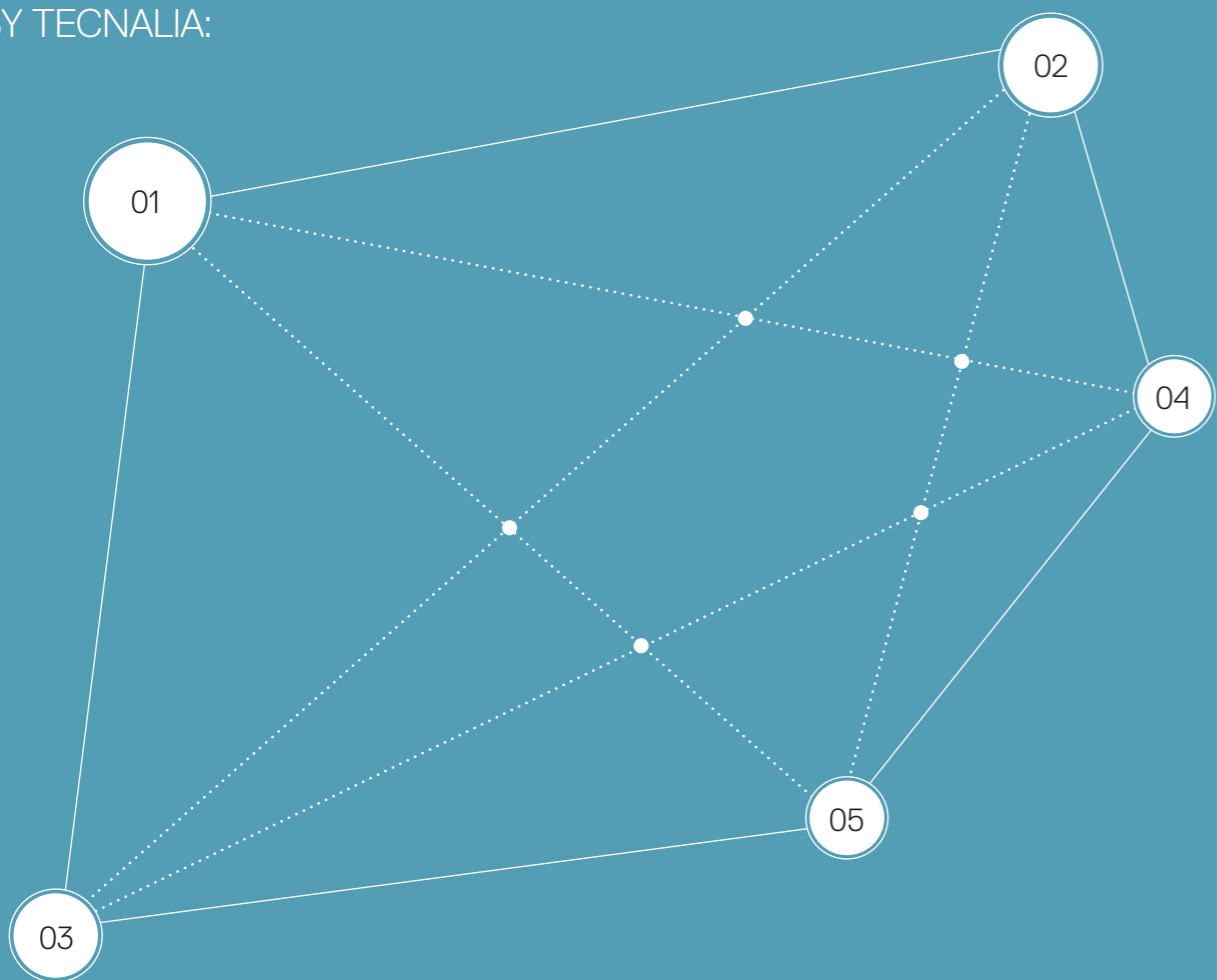
+ 3,000 M<sup>2</sup> OF FACILITIES

FULL-SERVICE CDMO



**MORE THAN 3.000 M<sup>2</sup> AT YOUR DISPOSAL FOR YOUR PHARMACEUTICAL PROJECT**

## SERVICES PROVIDED BY TECNALIA:



### 01. PHARMACEUTICAL DEVELOPMENT

- Galenic Development
- Analytical development and validation of analytical techniques
- ICH Stability Studies
- In-vitro* dissolution profiles comparative studies

### 02. MANUFACTURING

- Industrial Scaling
- Pilot Batches & Registration Batches
- Industrial Batches: Manufacturing for third parties
- Manufacturing of IMP and placebo for Clinical Trials

### 03. CLINICAL TRIALS

- Bioequivalences
- Pharmacokinetic Studies
- Nutritional Trials
- Clinical Validation
- Bioanalysis
- Phase I to IV
- External Studies Management

### 04. PHARMACOGENETICS

- Companion Diagnostic
- Genetic Testing

### 05. BIOCIDES EFFICACY ASSESSMENT AGAINST BLOODSUCKING ARTHROPODS WITH HIGH SOCIO-SANITARY IMPACT

- Personal protection biocides assessment against bloodsucking arthropods: vectors (mosquitoes and ticks) and with high socio-sanitary impact (head lice and bed bugs).

## OUR CERTIFICATION AND CONFORMITIES

Our pharma laboratories are certified in accordance to specific standards and practices:

- **ISO 9001.**
- **Good Manufacturing Practices (GMP)** - Pharmaceutical development and manufacturing.
- **Working under Good Clinical Practices (GCP)** - Clinical Trials Unit.
- **Spanish Agency of Medicines and Medical Devices (AEMPS)**, Inspection with positive result - Clinical trials and Bioanalysis.
- **Authorised and registered by local health authorities** - Genetic Testing.
- **ISO 13485.** Medical devices manufactures quality system.

**TECNALIA is your partner** from pharmaceutical development to pilot batch production scale including bioequivalence studies in our clinical trials unit.



TECNALIA offers **independent, efficient and cost effective testing and analysis services** that will accelerate the introduction of your pharmaceutical product to the market.

01

# PHARMACEUTICAL DEVELOPMENT

TECNALIA's Pharmaceutical Development Laboratory is accredited by the Spanish Agency of Medicines and Medical Devices (AEMPS) in **Good Manufacturing Practices (GMP)**.



Your partner for pharmaceutical development with **fast, flexible and tailored solutions.**



## GALENIC DEVELOPMENT

- Pre-formulation studies.
- Design and galenic development of innovative, generic and brand (OTC) medicines.
- Design and galenic development of new dosage forms.
- Compatibility studies of active ingredients and excipients.
- Design of manufacturing processes.
- Transfer of manufacturing technology and in-situ support.
- Expert reports.
- Patents study.

## ANALYTICAL DEVELOPMENT

- Development and validation of analytical techniques.
- Characterization of raw materials according to Pharmacopoeia.
- Quantification of active ingredients, impurities and degradation products in raw materials and medicines.
- Forced degradation studies.
- Monitoring of the first industrial manufacturing batches.
- In-vitro dissolution profiles.
- Discriminatory power of the dissolution media for the dissolution profiles.
- Transfer of analytical techniques.
- Metal impurities analysis by ICP-OES.

## STABILITY STUDIES

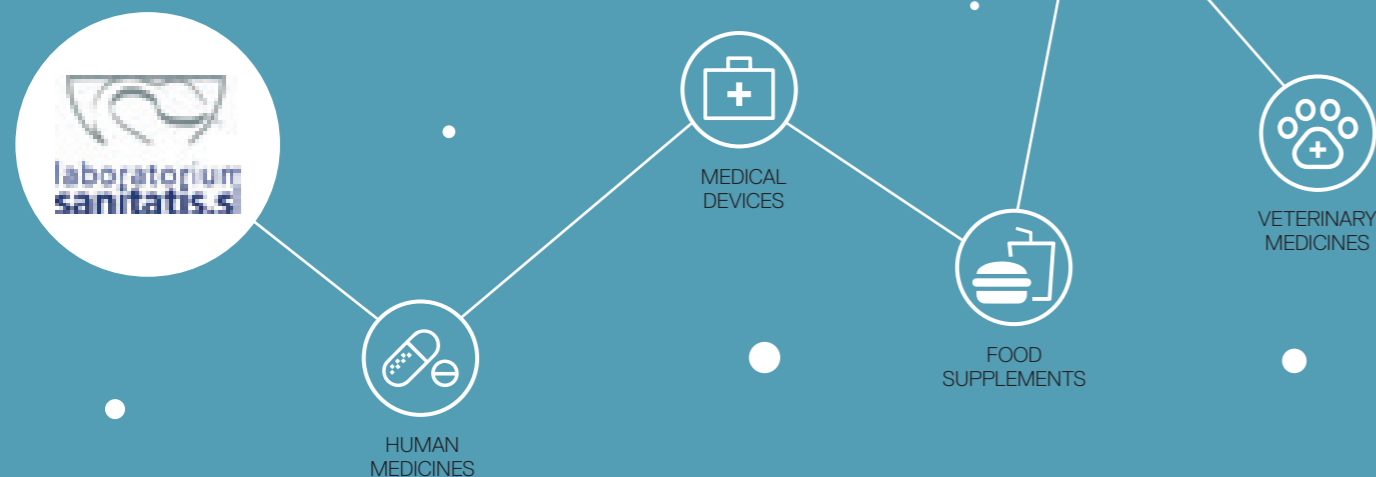
- ICH Stability Studies (Zone I to IV).
- Accelerated studies.
- Photostability studies.
- In use stability studies.
- On going stability studies.
- External management of stabilities.



With **more than 20 years of experience**, TECNALIA has the skills and the capacity to handle your **Stability Studies.**

# 02 GMP MANUFACTURING FOR THIRD PARTIES

For the past 20 years, TECNALIA, **Laboratorium Sanitatis (Labsan)**, has developed **core competencies and knowledge tailored to support contract manufacturing requirements** with major pharmaceutical industries and more specifically **specialized in Generic medicines.**



## SCALE UP

- Industrial Scale up.
- Scaling up from laboratory batches to industrial batches.
- Validation of new manufacturing and packaging processes.

## PILOT BATCHES

### FOR REGISTRATION

- Contract manufacturing in compliance with the principles and guidelines of GMP for medical products.
- Transfer of analytical techniques.

### FOR CLINICAL TRIALS

- Return, reconciliation and destruction of medicines.
- Contract manufacturing of placebos, medicines and food supplements.
- Design of blinding strategy.
- Labelling for primary and secondary packaging.
- Storage in GMP conditions.
- Shipping management to the different sites.
- Importation of active substances and medicines.

## INDUSTRIAL BATCHES

### FOR THIRD PARTIES

- Quality control and certification of active substances, excipients and finished products.
- Manufacturing in GMP conditions.
- Validation of cleaning processes.
- Analysis and batch release.
- Storage in GMP conditions.



## AUTHORIZED PRODUCTS & DOSAGE FORMS

### AUTHORIZED PRODUCTS

- Human medicines
- Medical devices
- Food supplements
- Cosmetics
- Veterinary medicines

### AUTHORIZED DOSAGE FORMS

**Solids**  
(tablets, coated tables, capsules...)

**Liquids**  
(solutions, syrups, drops...)

**Semi-solids**  
(creams, emulsions, gels...)



## EQUIPMENT

- Mixing: Rulon, V, Vima Cyclops.
- Granulation: High Speed, Oscillating.
- Drying: Static, Fluid Bed.
- Capsules filling: Manual, Macofar CD-40.
- Tableting machine: Kilian.
- Tablet coating: IMA-70 drum coating.
- Liquids: 100L, 2.400L reactors.
- Semisolids: 10L, 300L, Mixer.
- 1<sup>st</sup> Packaging:
  - Tube: Alu, PE.
  - Bottles: glass, PET.
  - Blister packing machine ALU/ALU PVC/ALU.
- 2<sup>nd</sup> Packaging:
  - Cartoner.
  - Labeling.

# 03 CLINICAL TRIALS

The Clinical Trials Unit is located at Araba University Hospital (HUA) in Vitoria-Gasteiz, with easy access to in-house facilities.

The Clinical Trials Unit can develop wide range of clinical trials in healthy volunteers and patients. The unit is approved and regularly inspected by the Spanish Agency of Medicines and Medical Devices.

Our clients range from large pharma industries to small companies.

18 beds, available for overnight stay and fully functional hospital ward with 24 h medical surveillance / monitoring.



## SERVICES



### BIOEQUIVALENCE STUDIES

We have extensive experience in bioequivalence developing of all kind of drugs, administered by different routes and experimental designs.

Different dosage forms:

- Oral dosage forms (oral suspensions, chewable tablets, tablets, capsules, sub-lingual forms, oral-dispersible tablets, etc.).
- Inhalation devices.
- Intra-nasal sprays.



### CLINICAL NUTRITION

Clinical trials designed to registre the safety and efficacy of active ingredients, food supplements and functional foods.

TECNALIA is focused in the design, implementation, coordination, monitoring and analysis of clinical trials of high quality.

Our Clinical Trials Unit has experience in developing clinical trials with nutritional supplements for top companies.



### PHASE I CLINICAL TRIALS

- First-in-Human (FIH).
- Pharmacokinetics (PK) / Pharmacodynamics (PD).
- Interactions (Drug / Food / Alcohol).
- Drug tolerability and safety.



### PHASE II TO IV CLINICAL TRIALS

TECNALIA collaborates with the specialties that comprise the HUA for phase II to IV clinical trials.



### TURNKEY PROJECTS

- Design and/or evaluation of the study documentation.
- Managing regulatory authorities and IRB / IEC submissions and approvals.
- Database design, data entry and queries management.
- Pharmacokinetics (PK) analysis, pharmacodynamic (PD) analysis and PK / PD relationship.
- Analysis and statistical reports.
- Writing and/or review of clinical study reports.



### EXTERNAL STUDIES MANAGEMENT

- Collaboration in the design of the study documentation and management of authorization and contracts.
- Monitoring.
- Management of the Trial Master File (TMF).
- Data management.
- Review of the Clinical Study Report (CSR).



# 04 PHARMACOGENETICS

The activities of TECNALIA's Molecular Biology Group on the Biomedical sector aim to bring **P4 Medicine (Predictive, Preventive, Personalized and Participatory)** to patients and professionals.

In this regard, the Genetics and Molecular Biology Laboratory devotes a significant portion of its resources to develop assays and *in-vitro* tests for disease diagnosis, prognosis and prediction of drug response (**Companion Diagnostics**).

## COMPANION DIAGNOSTICS

### 01. PERSONALIZED

- Proper treatment at the right dose.
- To the right patient / disease.
- At the right time.
- For the right outcome.

### 02. PREDICTIVE

- Prediction of response to therapy.
- Efficiency vs toxicity.

### 03. PREVENTIVE

Evaluate risk and predisposition to certain diseases. It allows the adoption of preventive measures to delay, or even eliminate, the occurrence of the disease or early diagnosis.

### 04. PARTICIPATORY

To involve the patient in the management of his/her disease: treatment options, prevention strategies, monitoring of the disease and risks.



## GENETIC TESTING

TECNALIA also develops a strong activity in the field of Genetic Testing, focused on **three main areas**:

01. **Diagnosis of Hereditary Syndromes** (tumoral and non-tumoral)
02. **Preimplantation Genetic Diagnosis (PGD)** for monogenic diseases
03. **Preimplantation Genetic Diagnosis of Aneuploidies (PGD-A) or Preimplantation Genetic Screening (PGS)**

### EQUIPMENT:

The Laboratory (220 m<sup>2</sup>) consists of three different areas, two of which are intended to the preparation and handling of samples and are equipped with systems to control air temperature, humidity and pressure.

Main equipment **includes**:

- Illumina NGS Sequencing Equipment.
- Microarray Scanner.
- Capillary Sequencer.
- Real Time PCR.
- Flow cytometer.

**TECNALIA's Genetics Laboratory is authorized and registered by authorities as genetic diagnosis supplier.**

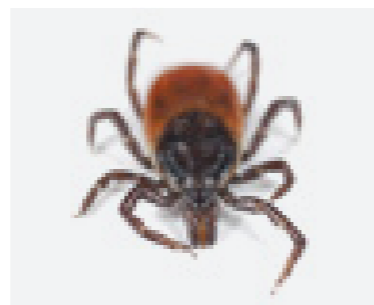
### GENETIC TESTING:

01. Diagnosis of diseases.
02. Pinpoint genetic factors associated to disease.
03. Disease prognosis and prediction.
04. Choose the best medicine and correct dose.
05. Discover genetic factors that increase the disease risk.
06. Identify disease associated genetic factors that could be passed to the next generation.

05

# BIOCIDES EFFICACY ASSESSMENT AGAINST BLOODSUCKING ARTHROPODS WITH HIGH SOCIO-SANITARY IMPACT

**PERSONAL PROTECTION BIOCIDES ASSESSMENT AGAINST BLOODSUCKING ARTHROPODS:**  
VECTORS (MOSQUITOES AND TICKS) AND WITH HIGH SOCIO-SANITARY IMPACT (HEAD LICE AND BED BUGS)



- **Skin repellents.**
- **In-vitro Bioassays of Pediculicides** (Head Lice and Nits).
- **Development and Efficacy Improvement of Personal Protection Fabrics** to prevent Bloodsucking Arthropods Bites.
- **Efficacy Assessment, Improvement and Development of Biocides** (Skin and Spatial repellents, Aerosols, Diffusers, Baits...).

## ACCREDITATIONS AND RECOGNITIONS

- **Ethic Committee** Approval (Donostia's Hospital, Gipuzkoa, Spain) for Volunteers Recruitment.
- Protocols and Facilities according to **WHO, EPA, ECHA, AEMPS.**

# CUSTOMERS REFERENCES

## PHARMACEUTICAL INDUSTRY

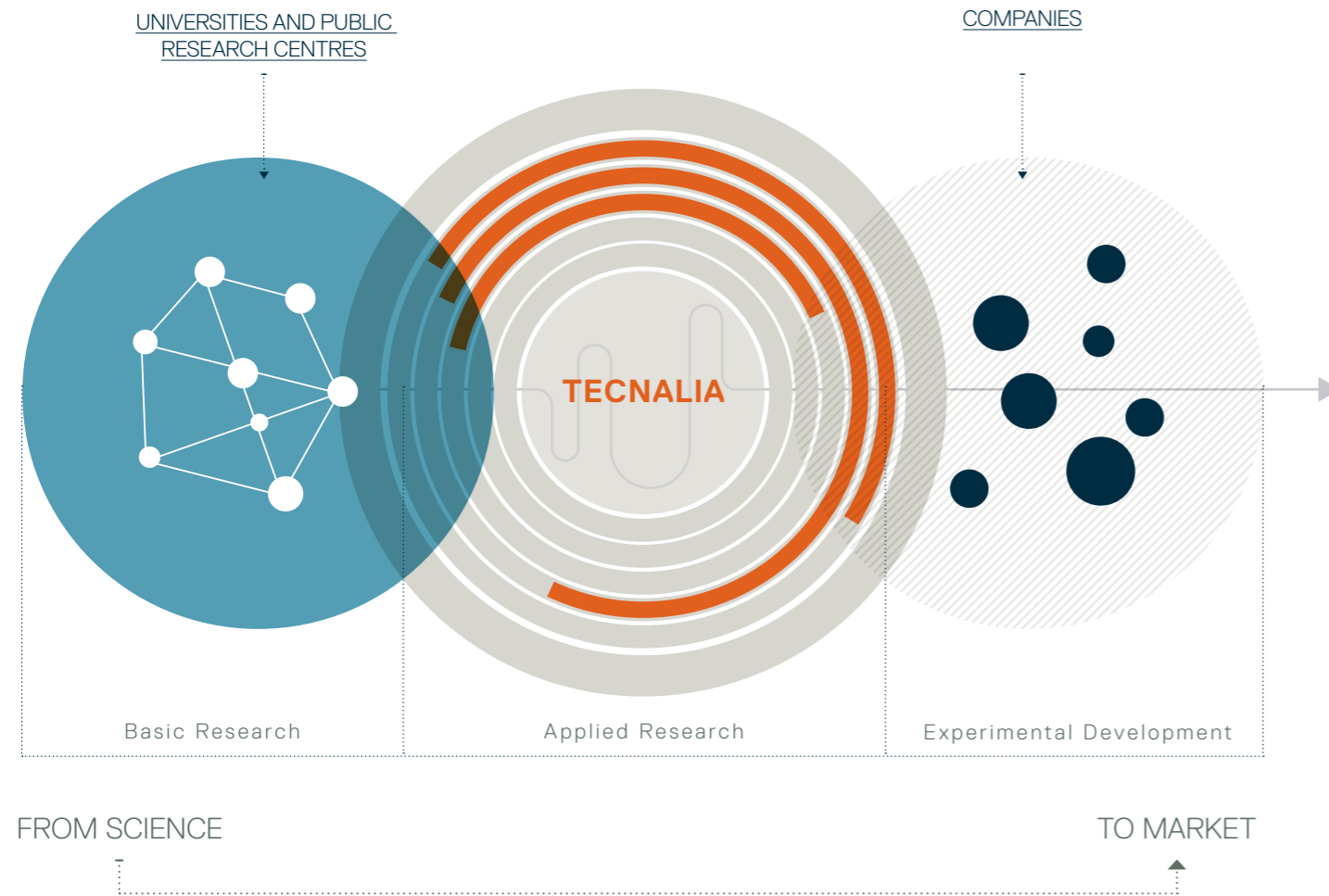
- |                                   |                                 |                                       |
|-----------------------------------|---------------------------------|---------------------------------------|
| → ADVANCED MARKER DISCOVERY, S.L. | → GRIFOLS                       | → PRAXIS BIOPHARMA RESEARCH INSTITUTE |
| → ALCURA                          | → HISTOCELL                     | → PRAXIS PHARMACEUTICAL, S.A.         |
| → AMNEAL                          | → KERN PHARMA                   | → QUIMUNSA                            |
| → ARISTO PHARMA                   | → KOROTT                        | → REVAHEALTH                          |
| → BILPER                          | → KYMOS PHARMA SERVICES, S.L.   | → ROXALL                              |
| → BIOMED                          | → LABORATORIOS ALDO UNIÓN       | → ROVI                                |
| → BIOSEARCH LIFE                  | → LABORATORIOS BILPER           | → SENDABIO                            |
| → BIOTECH, S.L.                   | → LABORATORIO ESTEDI, S.L.      | → SORIA NATURAL                       |
| → BTI                             | → LABORATORIOS BIOMENDI S.A.    | → STADA                               |
| → BUGGYPOWER                      | → LABORATORIOS CINFA, S.A.      | → STEMTEK THERAPEUTICS, S.L.          |
| → CAFOSA                          | → LABORATORIOS DIATER, S.A.     | → TEVA                                |
| → INSUD PHARMA                    | → LABORATORIOS FAES-FARMA, S.A. | → URIACH                              |
| → CHIESI                          | → LABORATORIOS FELTOR           | → UQUIFA                              |
| → CITEFRINE INTERNACIONAL         | → LABORATORIOS LICONSA, S.A.    | → VEGAL                               |
| → COLOR CENTER                    | → LEON FARMA                    | → VETPHARMA                           |
| → CYNDEA PHARMA, S.L.             | → LUSOMEDICAMENTA               | → VIDYA EUROPE                        |
| → DYNAKIN, S.L.                   | → MEDSIR                        |                                       |
| → ENNOGEN                         | → MESOESTETIC                   |                                       |
| → ESTEVE                          | → MINORIX                       |                                       |
| → EXPERIOR                        | → MITELOS                       |                                       |
| → FARMALIDER                      | → NEURONBIO                     |                                       |
| → FELTOR                          | → NOVO NORDISK PHARMA           |                                       |
| → FERRER                          | → NYRBOPLAN                     |                                       |
| → EXPERIOR                        | → OJER PHARMA                   |                                       |
| → FROSST IBERICA, S.A.            | → OMEGA PHARMA ESPAÑA           |                                       |
| → GALENICUM                       | → ONE DOSE PHARMA S.L.          |                                       |
| → GEISER-PHARMA, S.L.             | → PERSAN PHARMA                 |                                       |
| → GENFARMA                        | → PIERRE FABRE                  |                                       |
| → GES GENÉRICOS                   | → PROKREA                       |                                       |

## HEALTH AND SANITARY SERVICES

- |                                 |   |                       |
|---------------------------------|---|-----------------------|
| → BIOEF                         | → HOSPITAL DEL MAR                      | → IVF DONOSTIA        |
| → CER SANTANDER                 | → HOSPITAL DONOSTIA                     | → ONKOLOGIKOA         |
| → CLÍNICA ART                   | → HOSPITAL UNIVERSITARIO DE ARABA (HUA) | → QUIRON SALUD        |
| → CLÍNICA VICENTE SAN SEBASTIÁN | → INSTITUTO MARQUÉS                     | → REPRODUCCIÓN BILBAO |
| → FUNDACIÓN ELA                 |   |                       |

# TECNALIA

## IS A BENCHMARK RESEARCH AND TECHNOLOGICAL DEVELOPMENT COMPANY IN EUROPE

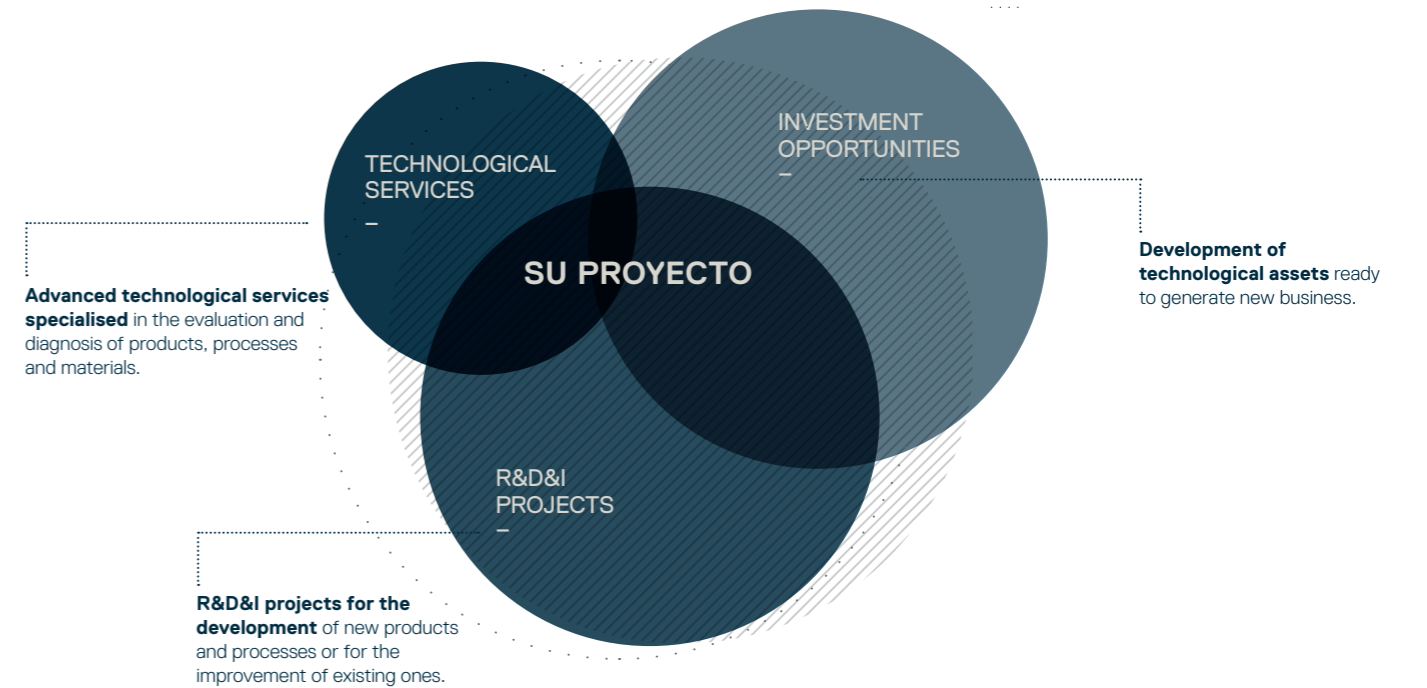


### MISSION

**We transform technology into GDP**

**We transform technology** into wealth to obtain beneficial visible results for companies, society, our environment and in short, for people.

### SERVICE OFFER



### SCIENTIFIC TECHNOLOGICAL CHALLENGES



#### ADVANCED MANUFACTURING

**New insights for the “Industry and Factory of the Future”** which will be smart and connected, automated and cognitive, flexible as well as sustainable, social and collaborative.



#### LOW-CARBON ENERGY

**Clean technologies and renewable energy play a key role** in advancing towards a more sustainable and efficient low-carbon society.



#### HEALTH AND AGEING

**Technology can play a key role in improving the quality of life of many people with physical disabilities or health problems.** We are committed to developing new devices, systems and products that encourage business activity in this sector.



#### DIGITAL AND HYPERCONNECTED WORLD

**We continue to evolve towards an increasingly connected and interactive world.** We are working in this context to give due response to the challenges of the Digital Economy and Cyber-Physical Systems.



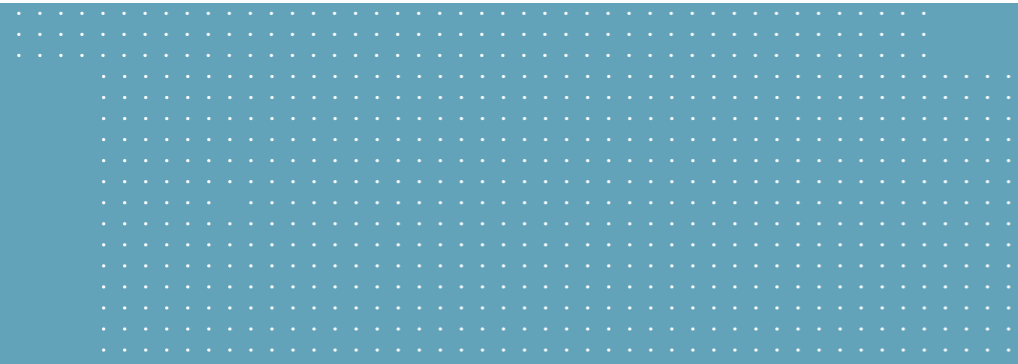
#### URBAN HABITAT

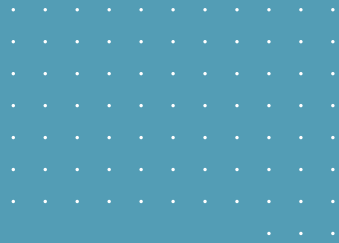
**We are committed to smart places and cities,** because we believe in their potential for progress, their innovation catalyst role and their ability to become an economic development driver.



#### CLIMATE CHANGE AND SHORTAGE OF RESOURCES

**Climate change impacts are already a reality.** We need to implement solutions and actions to minimise their effects: valorisation of waste and critical materials, emission reduction, circular economy, bioeconomy, etc.





# WE CAN DO SO MUCH **TOGETHER**

Our work is not understood without yours; we want to work together so your company can compete better. Because together, we can develop technologies that transform the present.

**The future is technological,  
let's share it!**



[blogs.tecnalia.com](http://blogs.tecnalia.com)

## **TECNALIA**

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