

YOUR PARTNER FOR INNOVATION IN LIFE SCIENCES

1.1

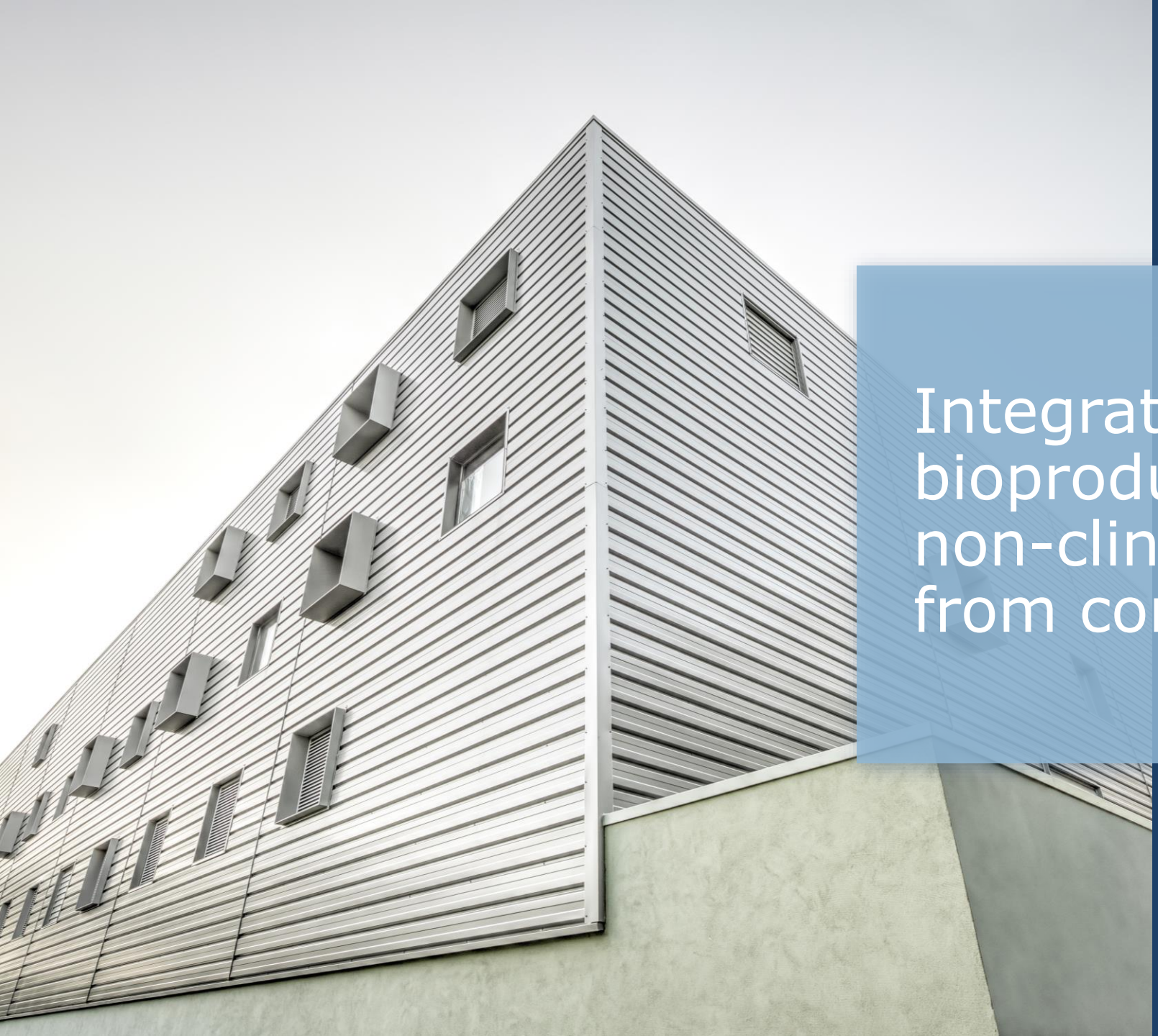
About us



Mission

CER Groupe is a Research Center supporting human health sector through comprehensive biologics discovery and non-clinical characterization CRO services





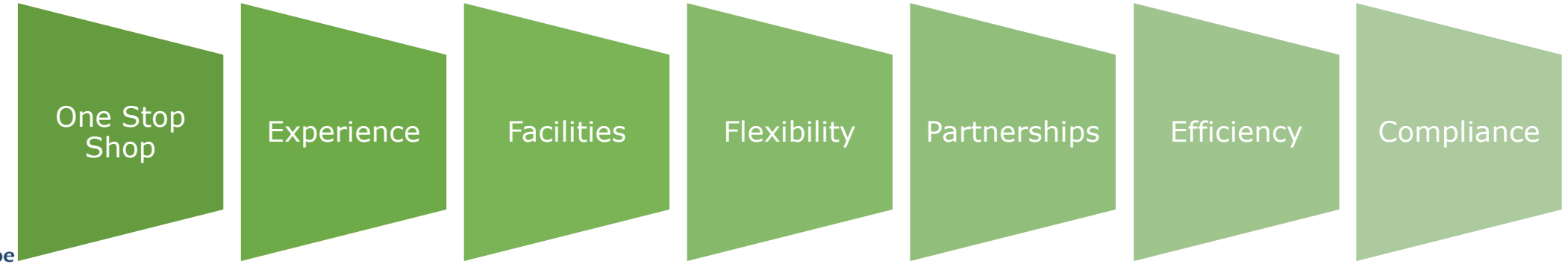
Vision

Integrated customized bioproduct discovery and non-clinical development from concept to IND

Our value proposal



Reliable partner



Belgian Life Sciences dedicated Collective Research Center

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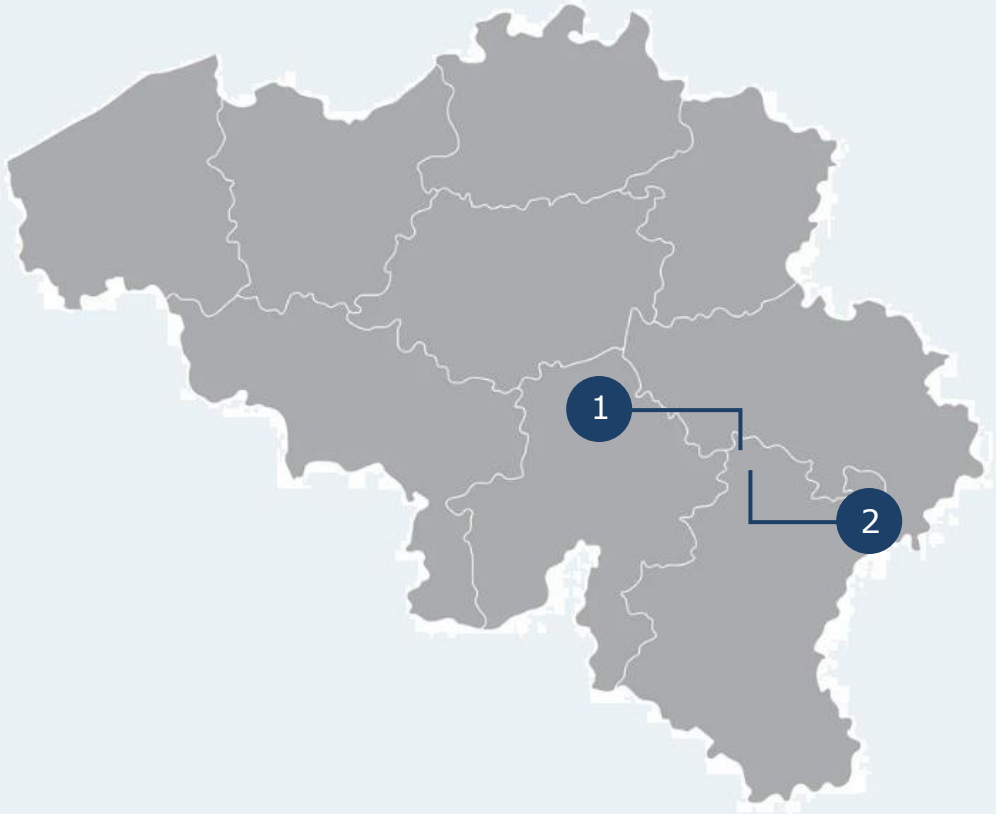
2





Since **1977**

200+ people

15000 sqm

1.2 Activities



Our Pillars



Bioproduction

Bioproduct Design, Lead selection, Optimization & USP/DSP



Non-clinical

In vitro/In vivo Characterization

PoC to GLP safety

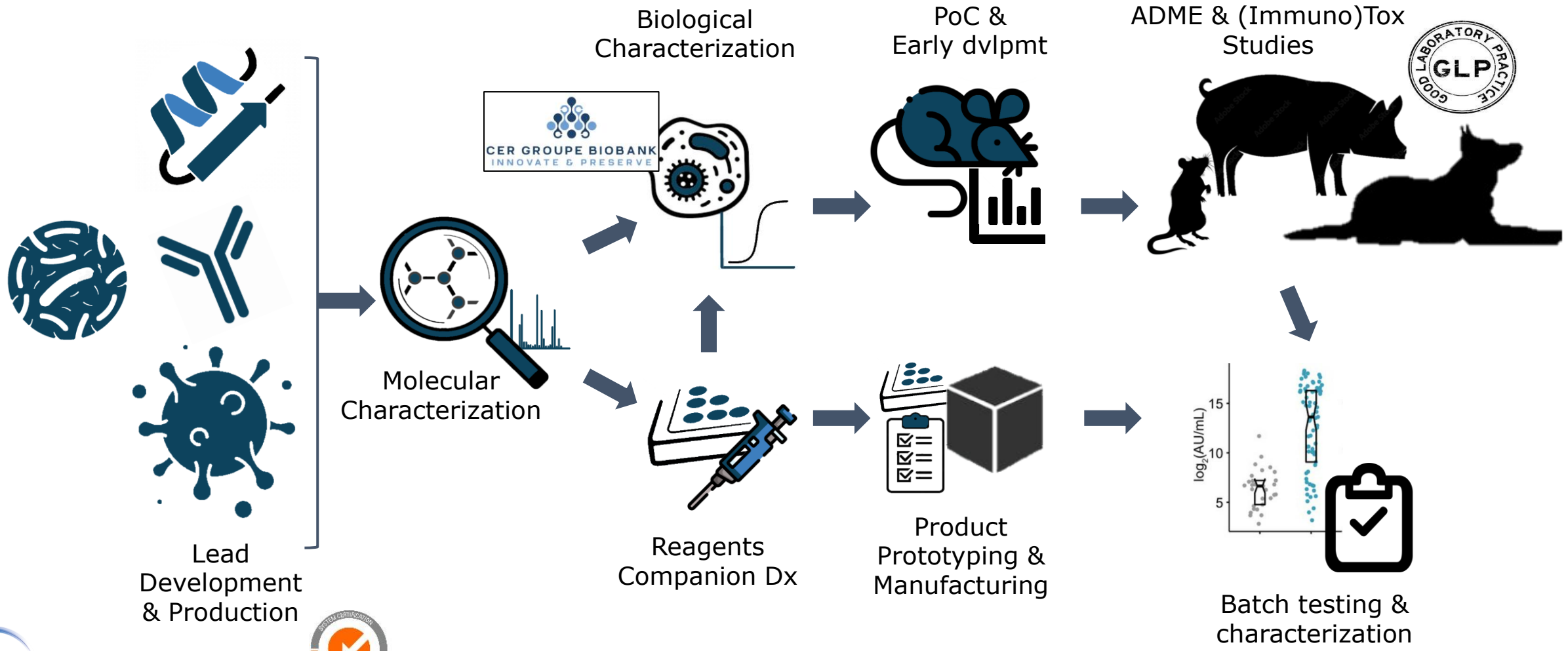


Analytical

Characterization – product, process, preclinical

Integrated, agile and quality partnerships

From concept to market



Specialty areas



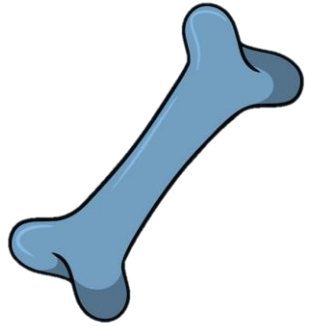
Vaccines & Immunotherapies



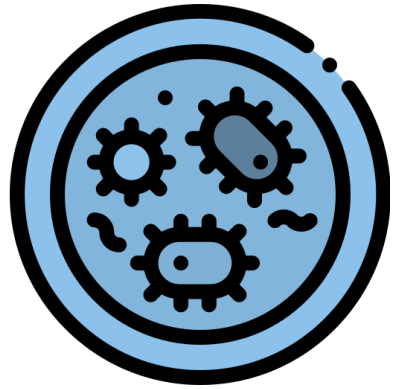
Oncology



ATMPs

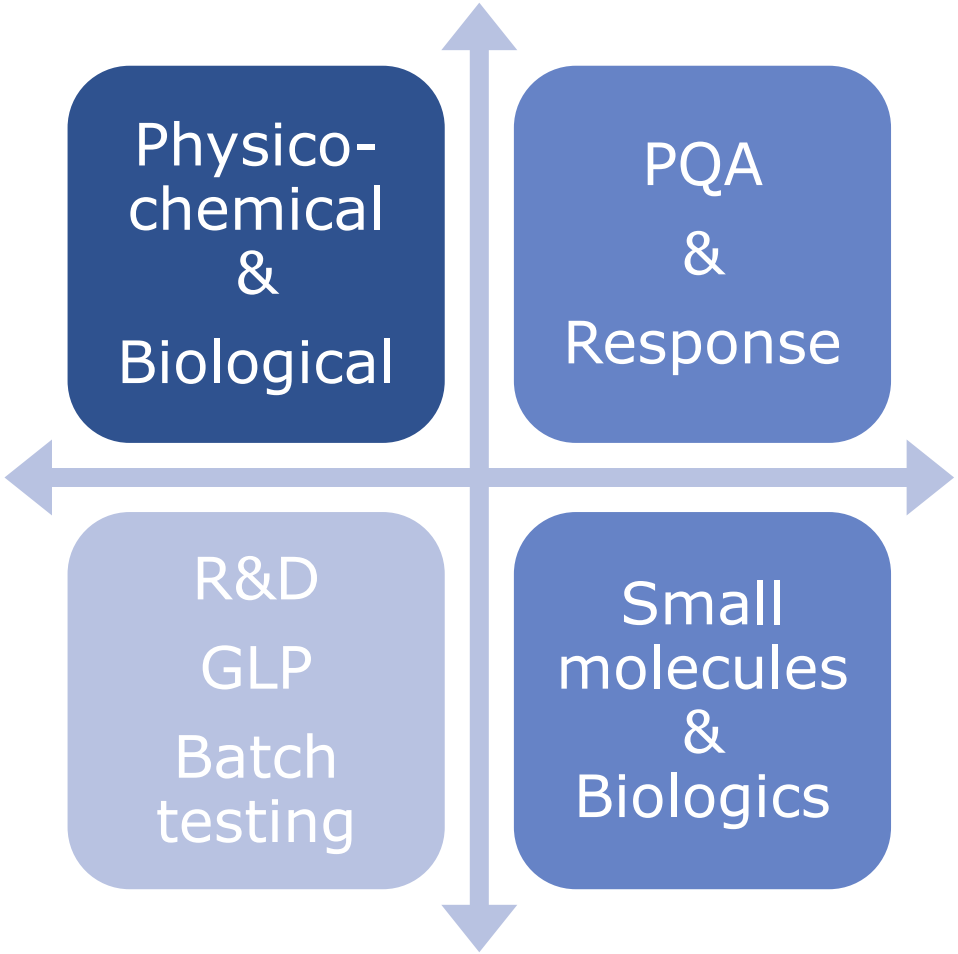


Osteoarticular



Infectiology

Analytical platform



Informed decisions through data



Analytical platforms - Bioproduction

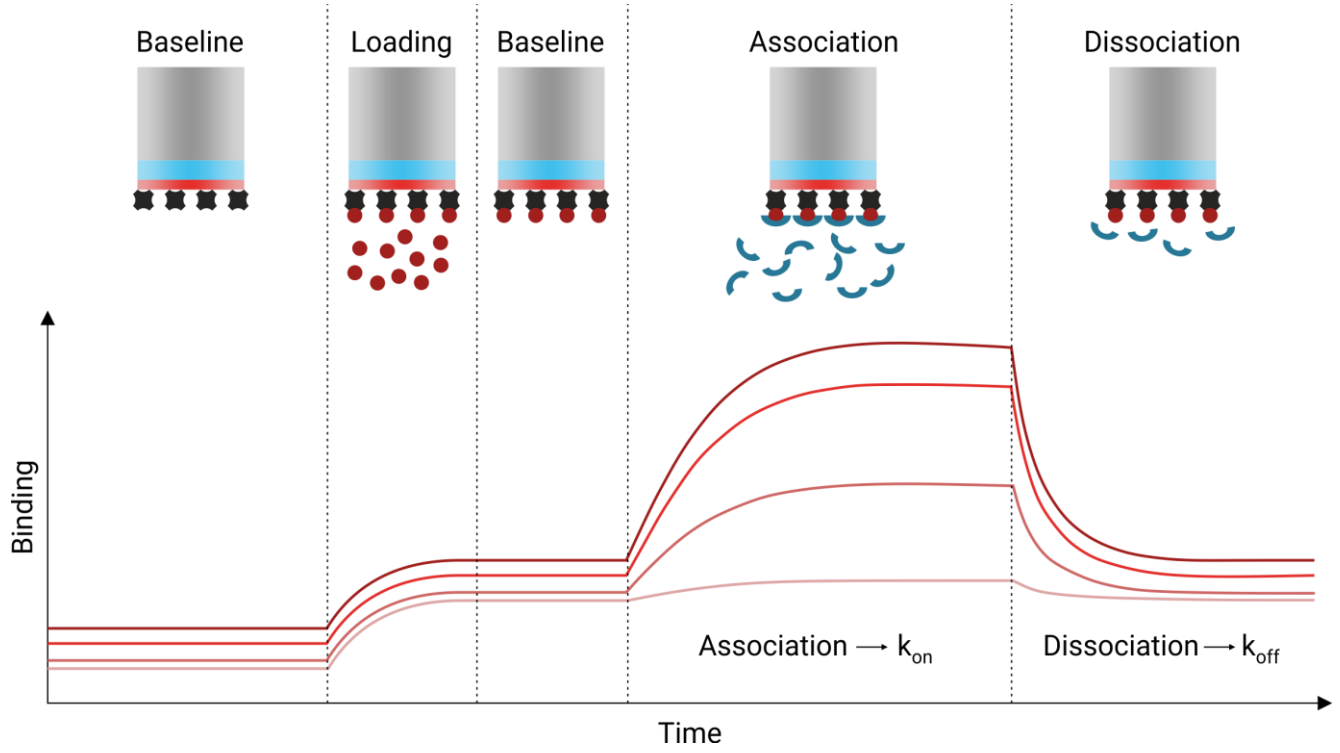
Quantitation & fine characterization
- **Affinity/X-react (BLI, IA, FACS)**
- **PQA (HR)MS**
- **Sequencing (VH/VL, de novo)**

Activity
- Enzymatic
- **Functional assays**
  - Cells, bacteria, virus, …

Selectivity/X-reactivity
- IA
- IAC-MS
- **BLI**
- FACS
- CBA

Stability (t°, pH, matrix, ..)
- **Spectroscopy (UV/vis, DSF)**
- **Studies (ICH)**

Solubility
- HPLC
- SDS-PAGE
- …



Quality : up to GLP/GLP-like

Confidential

Analytical platforms - Preclinical

Molecular interaction (BLI)
- Quantitative analysis

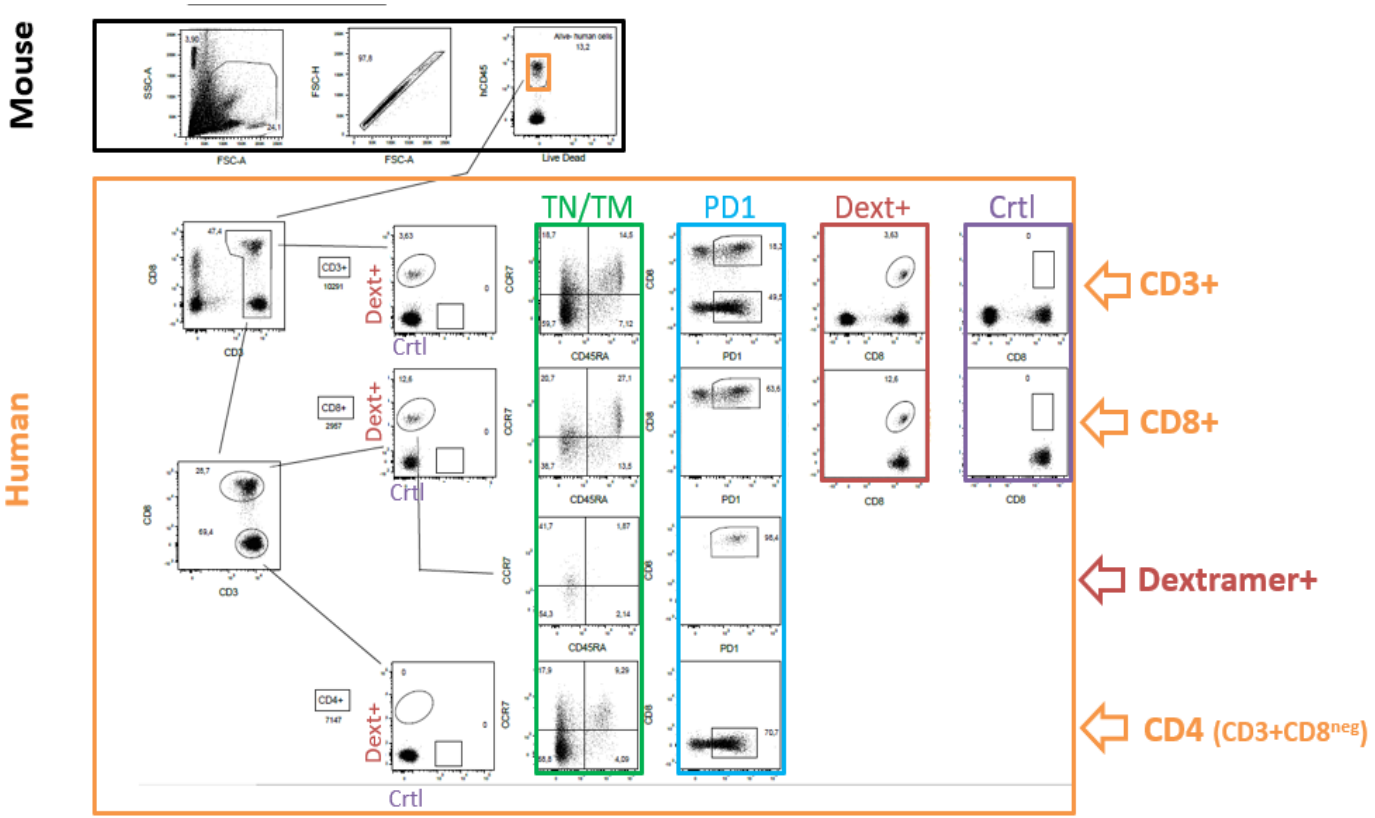
Molecular biology
- **Gene expression**
- Transcriptomics

Mass Spectrometry
- Small molecules & proteomics
- **Metabolomics**

Cell-based assays
- Cytotoxicity/proliferation (**biobank !**)
- **Immuno-inflammation-biofunctional** charact.

Flow cytometry/FACS
- **Phenotyping**
- Quantitative analysis
- Cell sorting

ImmunoAssays
- Quantitative analysis (cytokines, …)
- Titering



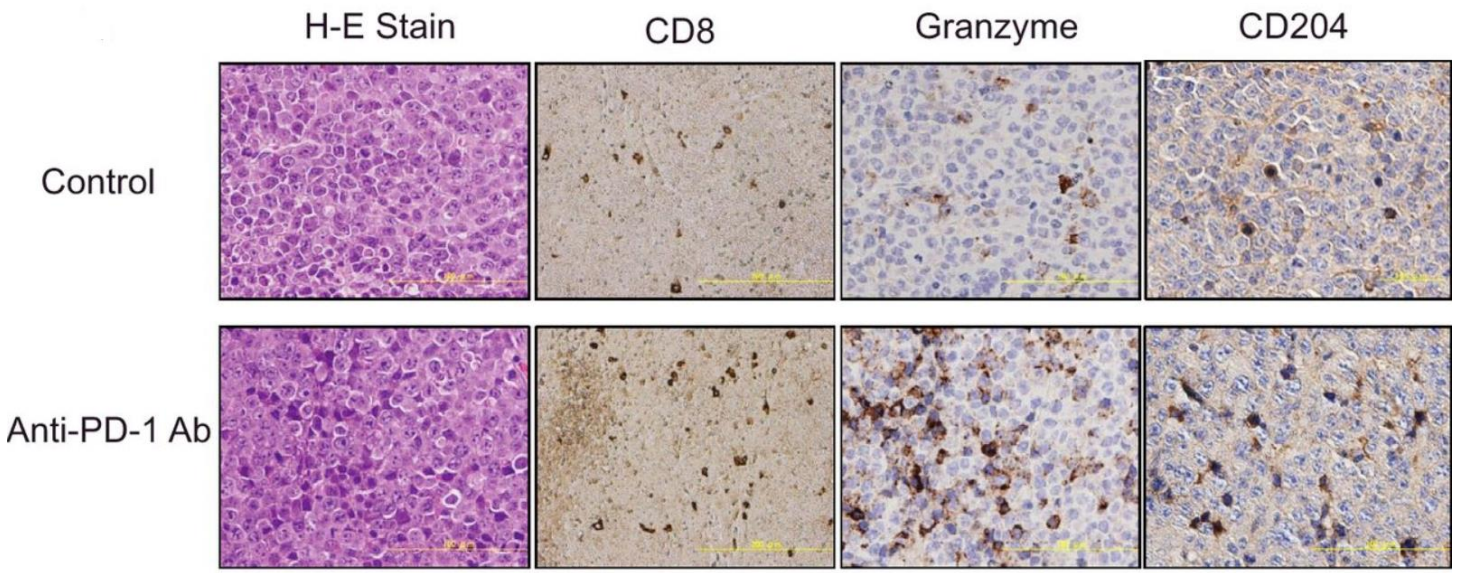
Quality : up to GLP/GLP-like

Confidential

Preclinical read-outs

Complete support

- CER platforms
  - Targeted small mol./prot. – metabolomics – immunomonitoring – gene expression – viro/bacteriology
- Trusted partner network
  - IHC – biochemistry – hematology – hemostasis – genomics – microbiome
  - R&D to GLP



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Preclinical read-outs – Metabolomics



Sample extraction

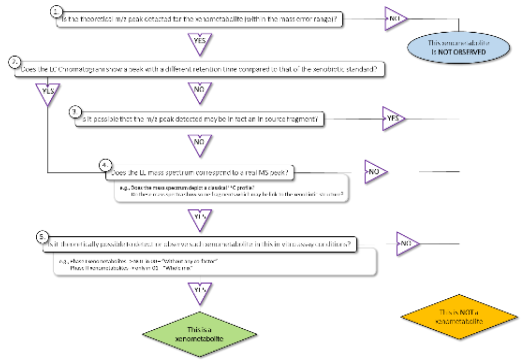
UHPLC-HRMS analyses



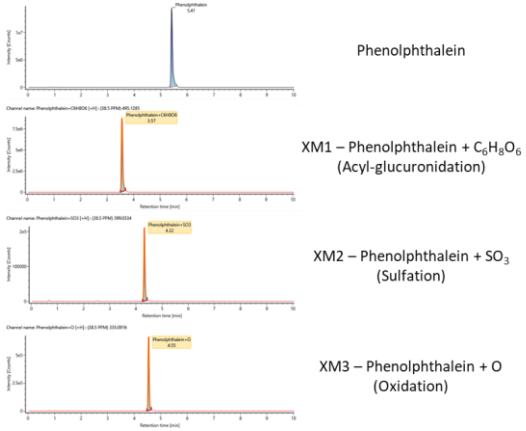
Data processing

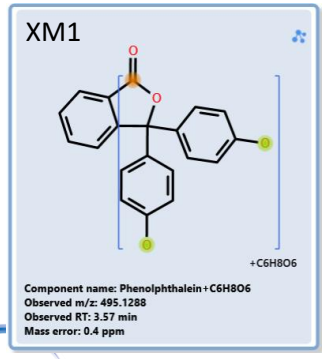
Name	Delta mass (Da)	Formula	Classifier
Reduction	2.0157	$+H_2$	Phase I
Oxidation	15.9949	+O	Phase I
Acetylation	42.0106	$+C_2H_2O$	Phase II
Sulfation	79.9568	$+SO_3$	Phase II
Glucuronidation	176.0321	$+C_6H_8O_6$	Phase II
Desaturation	-2.0157	$-H_2$	Phase I

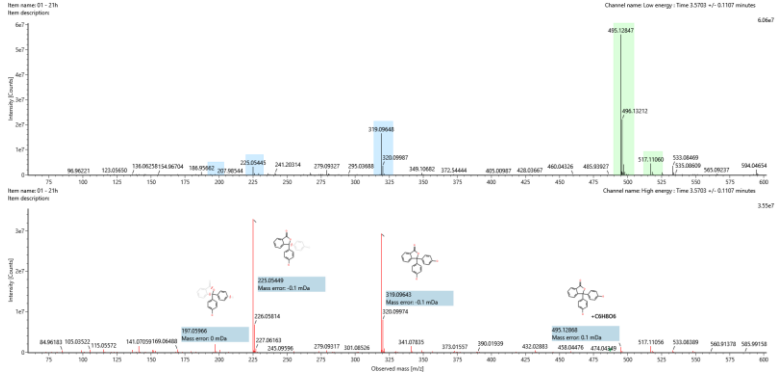
Data reviewing



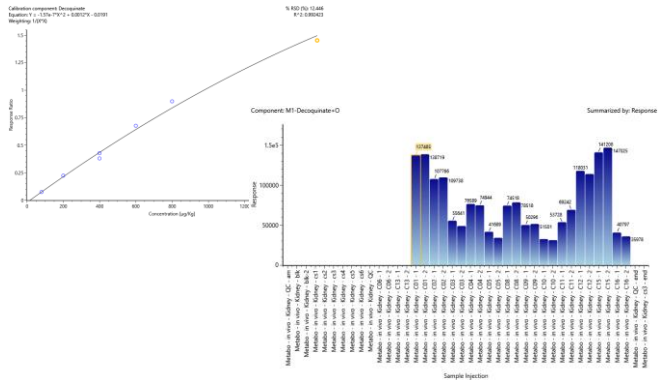
Xenometabolite ID

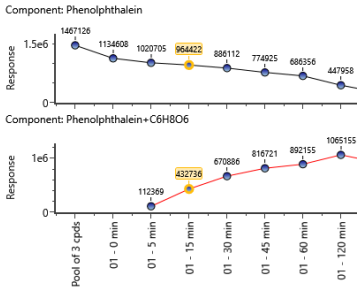






Semi-quantification





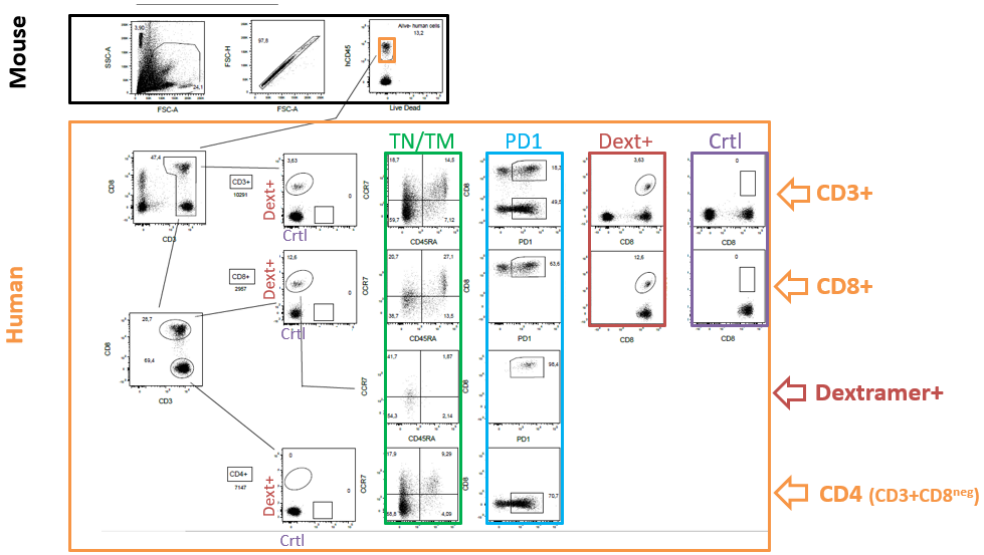
Kinetics

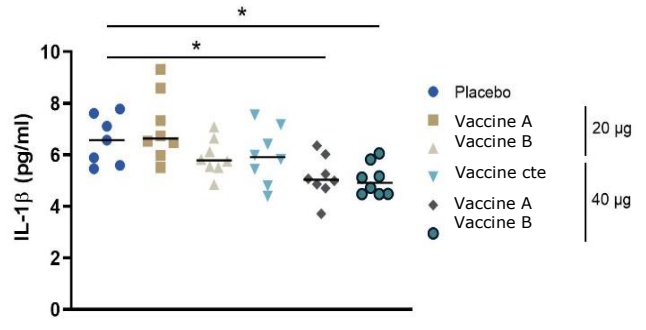
Preclinical read-outs - Immunomonitoring

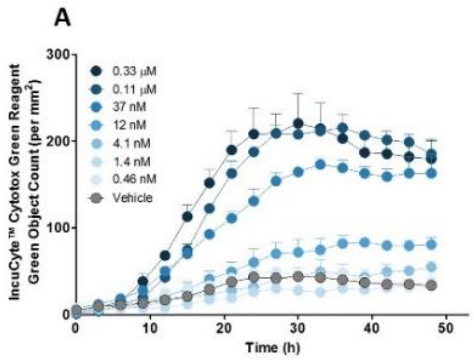
Various applications

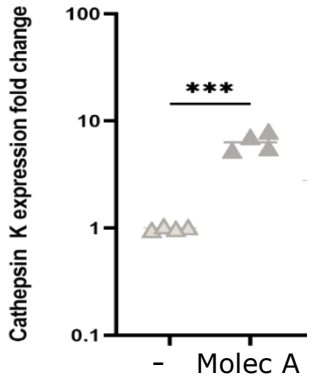
- Immune response
- Gene expression
- Multiparametric phenotyping
- TCR seq
- Mechanism of action
- Inflammatory response
- Toxicity
- …

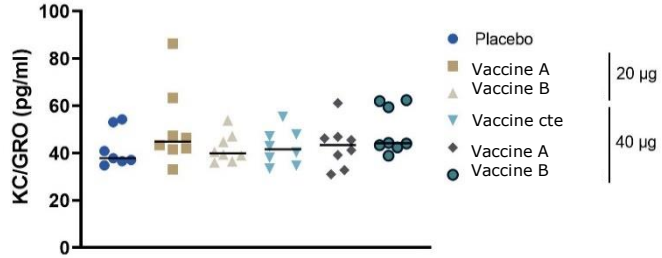
➔ Customized approach











Confidential

Bioproduction platform

Workflow

- Design, Discovery & Development
- Characterization
- Manufacturing for preclinical Tx or commercial Dx
- Process dev & digitalization

Scope

- Conjugates
- Antibodies
- Proteins/Enzymes
- Biobetters
- Virus/VV
- Cell lines

Factories

- HEK293 (**HEKsPer-T**)
- CHO
- *E. coli*
- *In vivo*
- Hybridoma
- Various cell lines for viruses



Strain engineering

Microbial engineering

- *Biomanufacturing (E. coli or custom)*
- *Probiotics (Lactobacillus & others)*

Targets

- Microorganisms
- Derived products (enzyme, OS, peptides, …)

Workflow

- 2 microbiology sites
  - Food vs Non-food, spore vs non-spore
- Random/targeted/HT evolution
- Colony picker
- Characterization platform
  - Biomanufacturing
  - Quality attributes





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Recombinant expression

Pre-study & Design → Feasibility Study → USP/DSP optimization → Upscaling → Characterization → Routine production

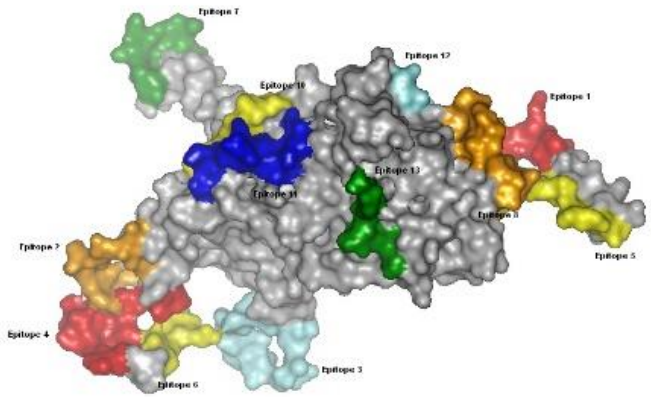
Strategies

- √ Host selection
- √ Computational biology (biobetters)
- √ Expression strategy (incl. bodies, peri, secret., co-expression)
- √ Extraction optimization
- √ Purification strategy (tag, custom, polishing)
- √ Refolding strategies (chaperones, chemicals, UF/DF)

Expression systems

- *E. coli*
- HEKsPer-T
- CHO

(+ Native extraction)



➔ Fit-for-purpose strategy & bioguided optimization approach

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Antibodies dvlpmt & manufacturing

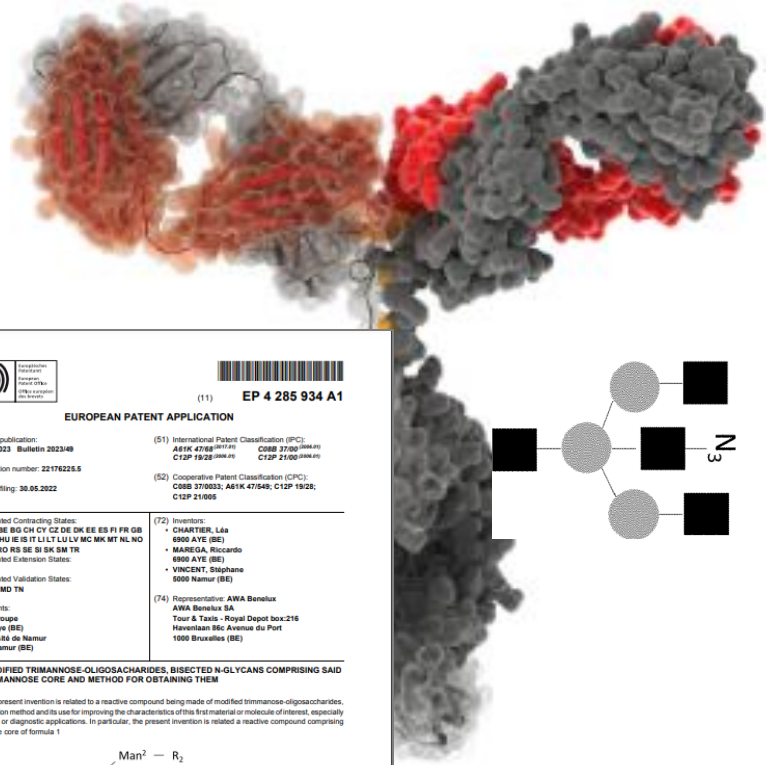
Relevant immunogens & antigens

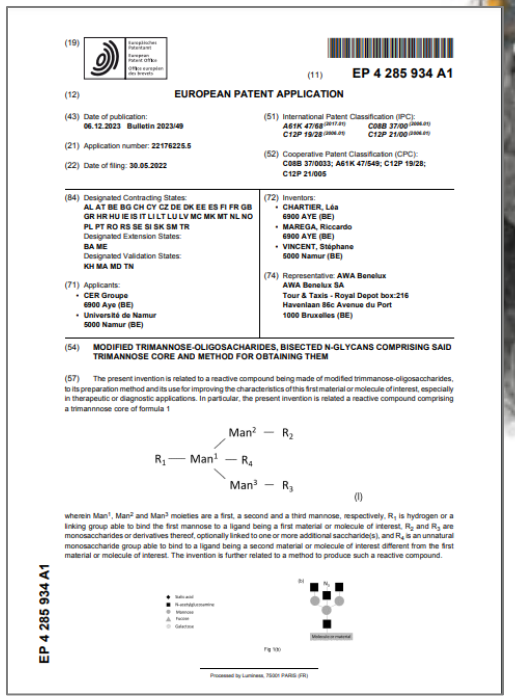
+

Advanced screening strategies

=

Best-in-class products





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(54) MODIFIED TRIMANNOSE-OLIGOSACCHARIDES, BISECTED N-GLYCANS COMPRISING SAID TRIMANNOSE CORE AND METHOD FOR OBTAINING THEM

(57) The present invention is related to a reactive compound being made of modified trimannose-oligosaccharides, to its preparation method and its use for improving the characteristics of this first material or molecule of interest, especially in therapeutic or diagnostic applications. In particular, the present invention is related a reactive compound comprising a trimannnose core of formula 1

$$R_1 — Man^1 \begin{cases} — Man^2 — R_2 \\ — R_4 \\ — Man^3 — R_3 \end{cases} \quad (I)$$

wherein Man^1, Man^2 and Man^3 moieties are a first, a second and a third mannose, respectively, R_1 is hydrogen or a linking group able to bind the first mannose to a ligand being a first material or molecule of interest, R_2 and R_3 are monosaccharides or derivatives thereof, optionally linked to one or more additional saccharide(s), and R_4 is an unnatural monosaccharide group able to bind to a ligand being a second material or molecule of interest different from the first material or molecule of interest. The invention is further related to a method to produce such a reactive compound.

EP 4 285 934 A1

EP4285934A1

Confidential

Polyclonal antibodies

Multi Species

>10KL serum /year

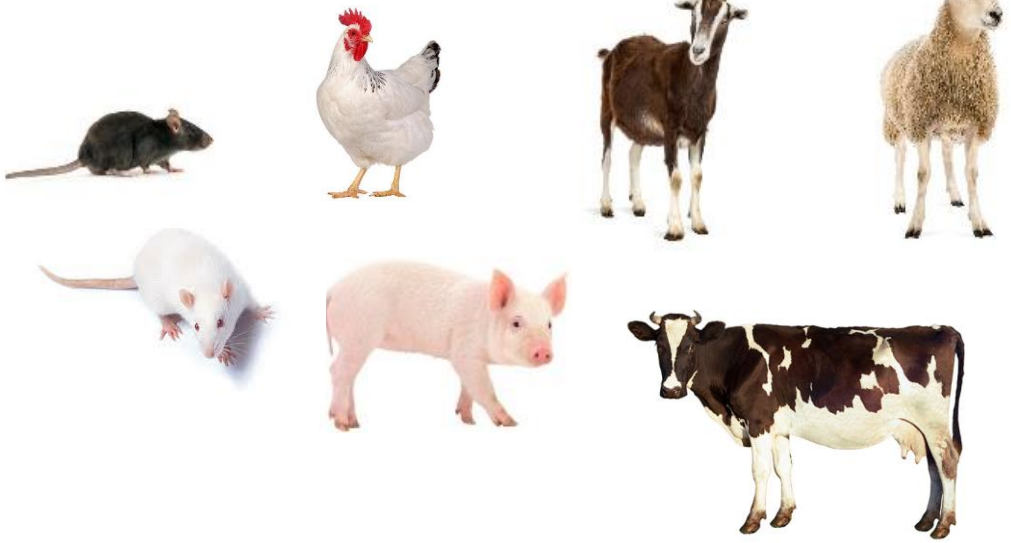
R&D Dx Tx

Haptens
DNA
Peptides
Proteins
Bacteria
Viruses

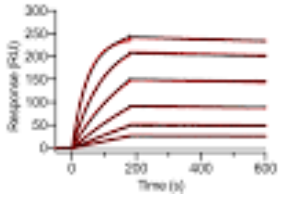
ML/Bioinfo boosted

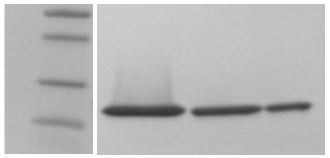
Up to kgs





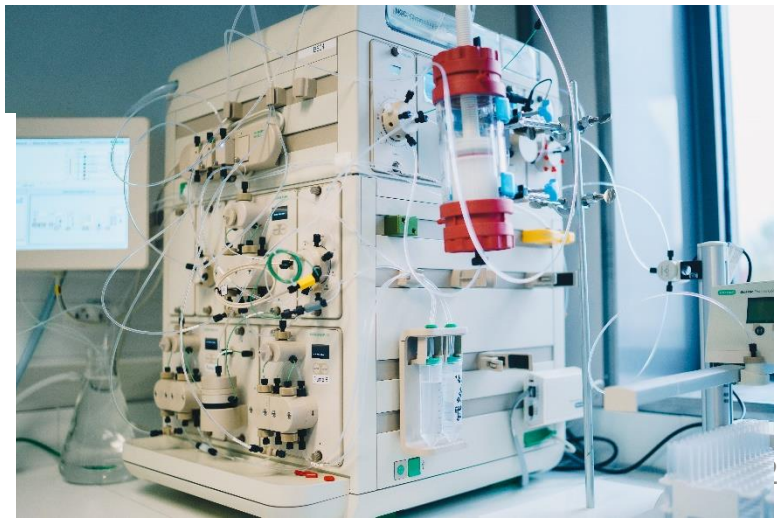
Characterization







DSP



Monoclonal antibodies

Mouse
Rat
Rabbit

Hybridoma
Or
Recombinant expression



RNA
Or
de novo
seq

Haptens
DNA
Peptides
Proteins
Bacteria
Viruses

Chimera

From
mg to
> 10 g

Fusion

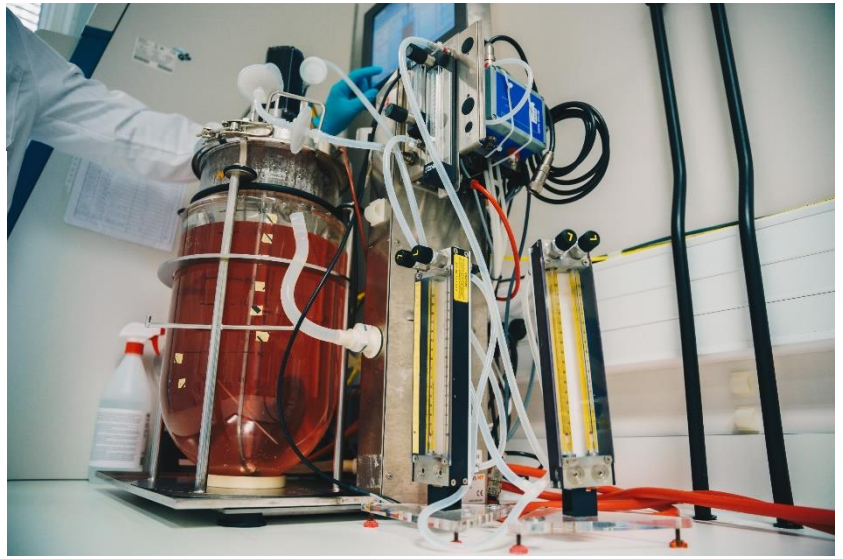
B cell screening



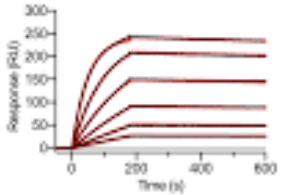
Hybridoma (mouse/rat)

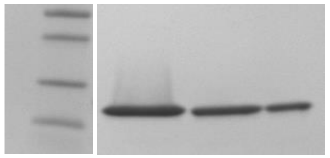
VH/VL seq (rabbit)

USP/DSP (HEKsPer-T)



Characterization







Camelids nanobodies VHH



Affinity screening by BLI

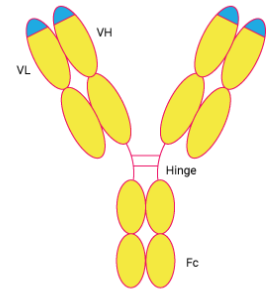
Camelids in house

HTS Variant generation

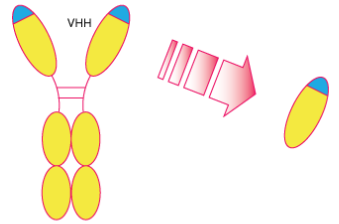
E. coli expression

Functional screening

Integrated



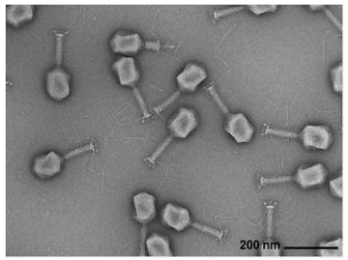
Conventional antibody (Ab)



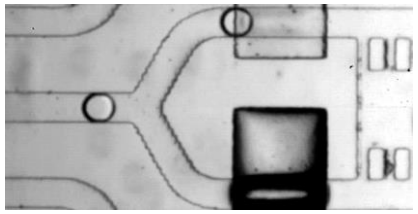
Heavy chain antibody (HcAb)

Nanobody

Phage display



B cell sorting (β test)



Hit to lead

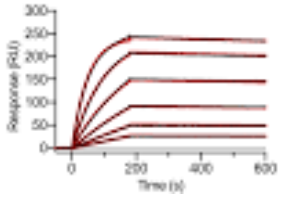


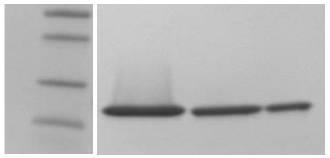
USP/DSP





Characterization

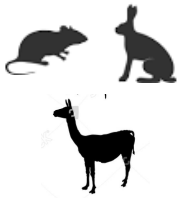


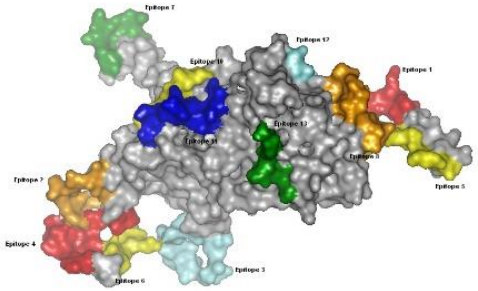


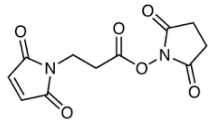


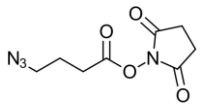
Bioconjugation activities

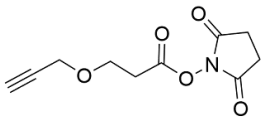
Immunogens → Sample clean-up → Dx reagents (vitro/vivo) → Tx leads → Functional Activity → Biological Activity

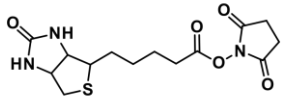


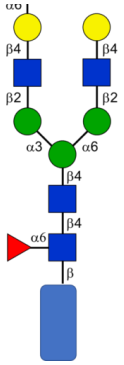


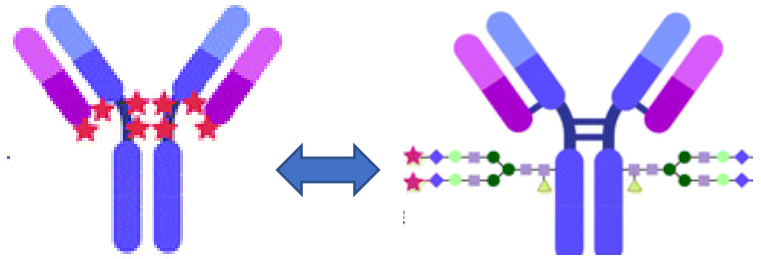


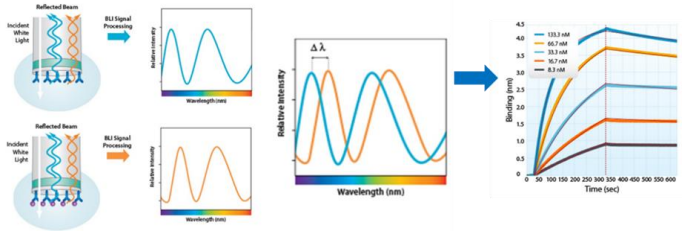


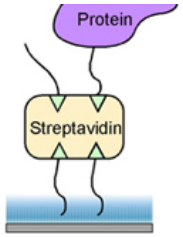


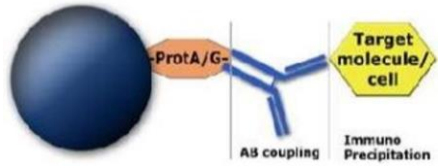


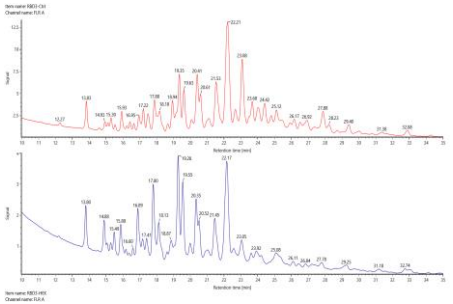












Objectives ➔ Target/DOL/IRF ? ➔ Customized bioconjugate development strategies

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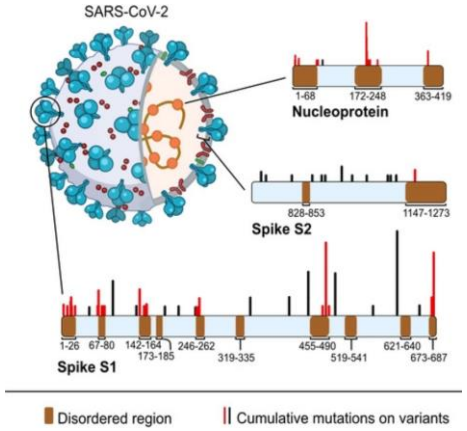
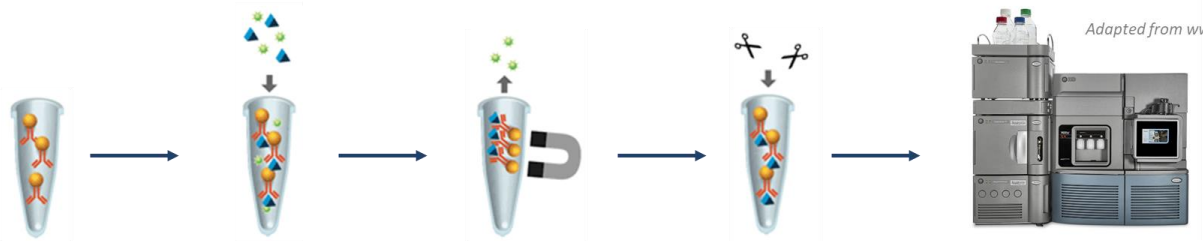
Bioconjugation activities

Immunogens | Sample clean-up | Dx reagents (vitro/vivo) | Tx leads | Functional Activity | Biological Activity

- High MS signal peptides
- UK variant specific mutations (20I Alpha, V1)
- South African variant specific mutation (20H Beta, V2)
- Brazilian variant specific mutation (20J gamma, V3)
- Indian variant specific mutation (21A Delta)
- No variant specific mutations





Adapted from www.bio-rad.com

```
        10         20         30         40         50
MSDNGPQNQR NAPRITFGGP SDSTGSNQNG ERSGARSKQR RPQGLPNNTA
        60         70         80         90        100
SWFTALTQHG KEDLKFPR GQ GVPINTNSSP DDQIGYYRRA TRRIRGGDGK
       110        120        130        140        150
MKDLSPRWYF YYLGTGPEAG LPYGANKDGI IWVATEGALN TPKDHIGTRN
       160        170        180        190        200
PANNAAIVLQ LPQGTTLPKG FYAEGSRGGS QASSRSSSRS RNSSRNSTPG
       210        220        230        240        250
SSRGTSPARM AGNGGDAALA LLLLDRLNQL ESKMSGKGQQ QQGQTVTKKS
       260        270        280        290        300
AAEASKKPRQ KRTATKAYNV TQAFGR RGPE QTQGNFGDQE LIRQGTDYKH
       310        320        330        340        350
WPQIAQFAPS ASAFFGMSRI GMEVTPSGTW LTYTGAIKLD DKDPNFKDQV
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ILLNKHIDAY KTFPPTEPKK DKKKKADETQ ALPQRQKKQQ TVTLLPAADL
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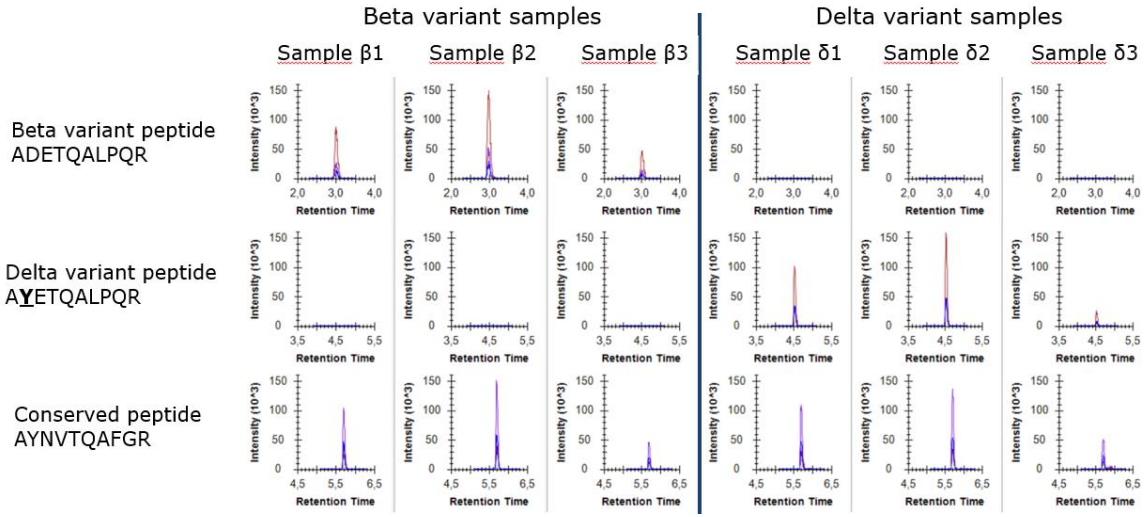


Bioprocessing and manufacturing activities

USP platform

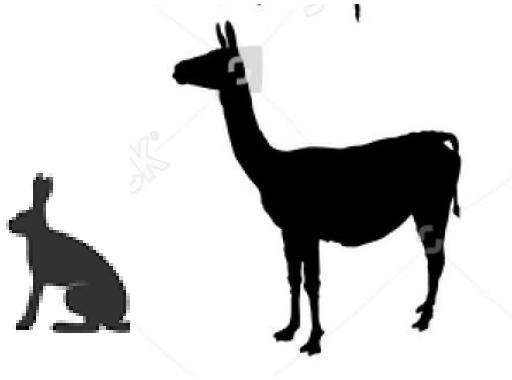
- In vivo
  - >50.000 rabbits/y.
  - 15000 sqm (goat – sheep – cow – llama - …)
- Bacterial
  - >50 ShF screening platform
  - 10l STR BioR (BioStatB Sartorius)
- Mammalian
  - >100 roller bottles
  - >50 ShF screening platform
  - Ambr250 4 modules (Sartorius)
  - 10l STR BioR (LabFors4 Infors)
  - Fixed-bed bioR (Scale-X Univ. Tech.)

DSP platform

- FPLC
- TFF
- Freeze-drying

Services

- Early process optimization (DoE, transfer to BioR)
- PQA optimization
- Routine manufacturing

















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Pharming facilities





+ rabbits, sheep, llama, pigs, poultry ➔ Antibodies, native proteins or other biologics

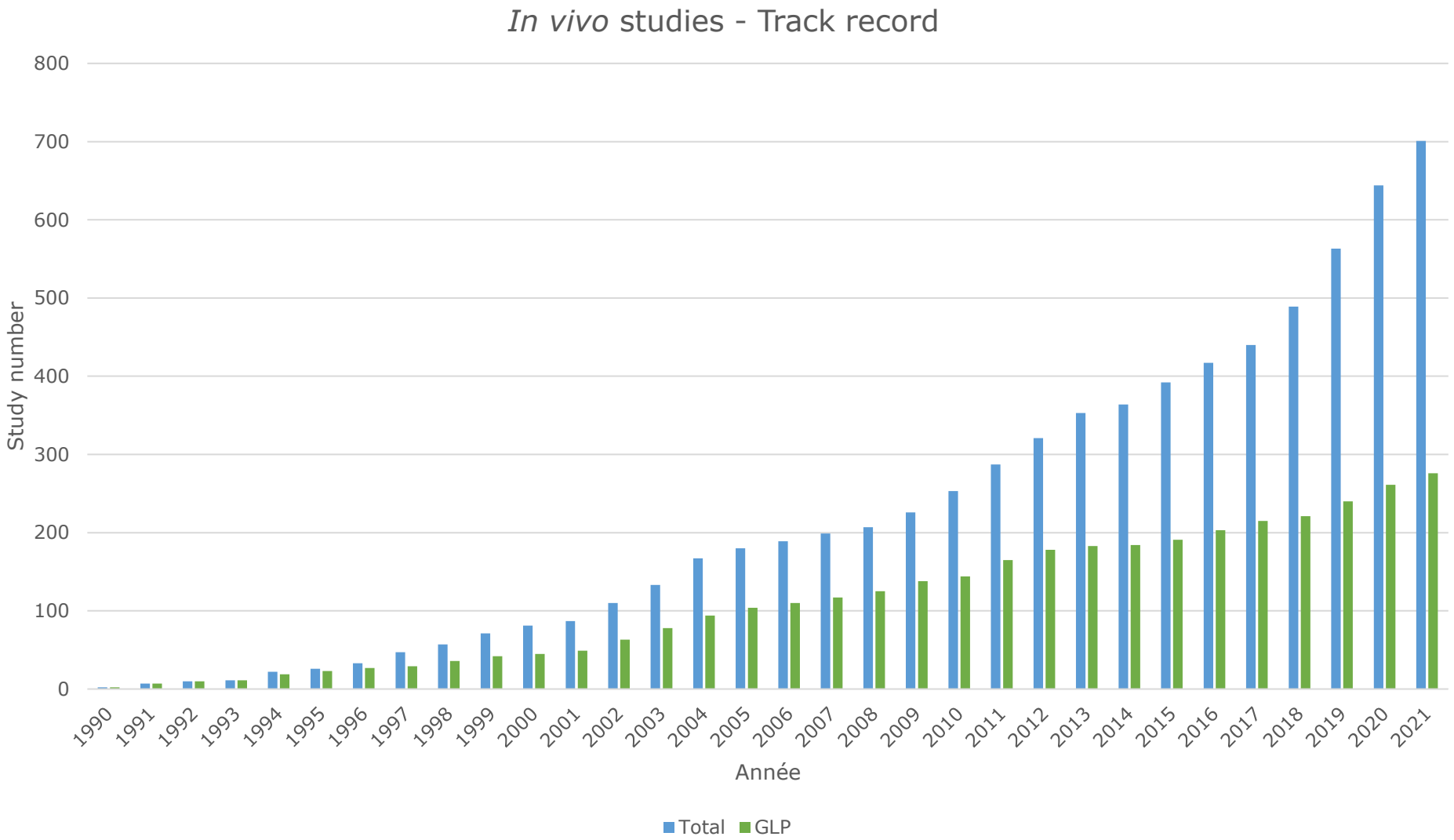
Preclinical platform

- ✓ State-of-the-art infrastructure meeting highest standards
  - *In vitro :* real-time cell imager
  - *In vivo* : Hygiene - Ethics - Animal welfare – Biosecurity
- ✓ GLP certification
- ✓ Facilities
  - SPF/SOPF housing for immuno models
  - BSL1 conventional housing
  - BSL2/BSL3 infectiology facilities
- ✓ Custom solutions
- ✓ Fully integrated offer
  - Item preparation
  - Biologics for model development
  - Analytical platforms



Confidential

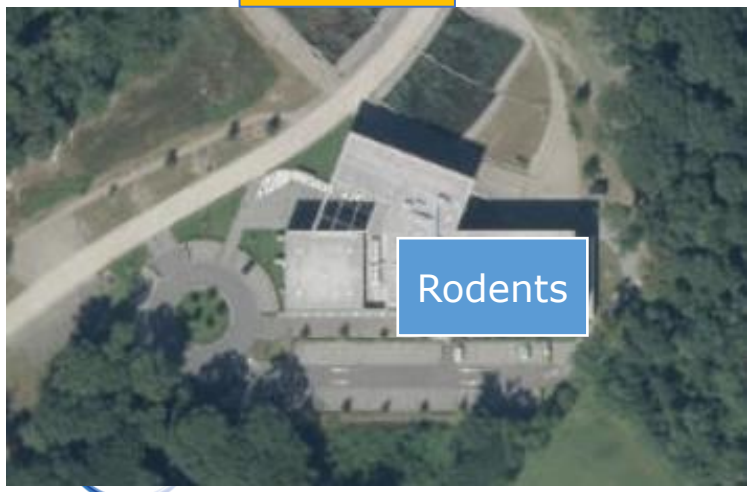
Preclinical platform



Non-Clinical platform
Our facilities

Species	Surface (sqm)
Rodents	~1.500
Rabbits	~10.000
Dogs	~1.000
Large animals	~2.500
TOTAL	~15.000

Aye



Marloie



Non-Clinical platform
Our facilities

Surfaces

	Facility	Surface (sqm)
***In vivo* facilities**	SPF	~11000
	BSL-1	~1000
	BSL-2	~2500
	BSL-3	~375
	Total	**~15000**

➔ Flexible housing for most species depending on project scope, duration and BSL level

+ 3000 sqm of laboratories (analytics & production)

Track record

Species	Managed cohort size (n)
Mouse	250
Rat	150
Guinea pig	120
Rabbit	120
Hen	80
Dog	30
Sheep	40
Goat	40
Pig	60
Cow	40
Horse	2
Llama	25

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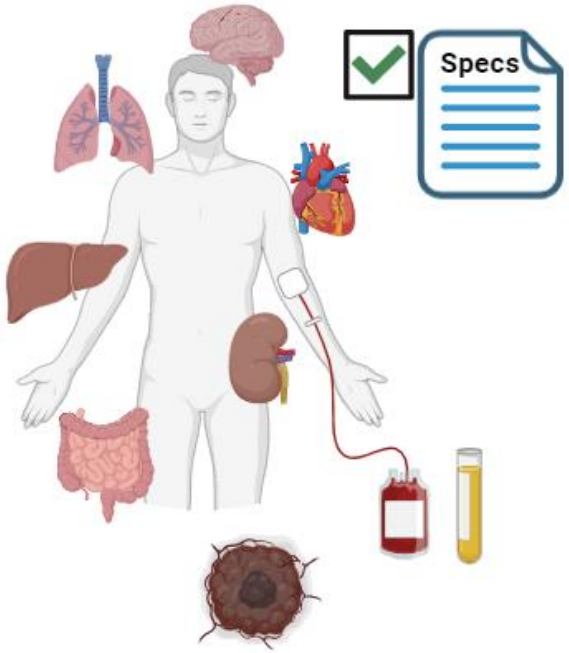
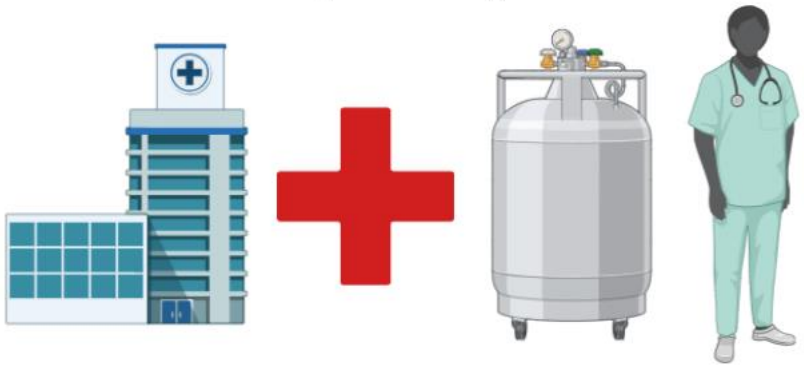
Biobank Services : Innovate & Preserve

1. Define sample specifications



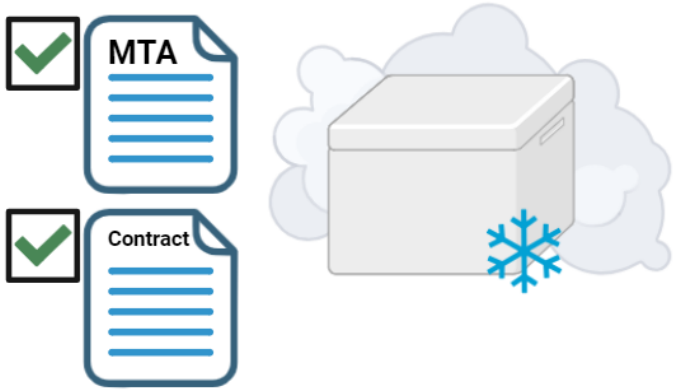
- ***Specifications sheet (by sponsor)***
- *Blood or derivatives*
- *Tissues, gamètes, embryos, bodyfluids*
- *Tumors*
- *Custom characterization*

2. Identify sourcing modalities



- *Croix-Rouge (MTA OK)*
- *Clinical studies*
- *External Biobanks (hospitals, CRO)*
- *Custom protocol*

3. Contractualize and organize sample transfer

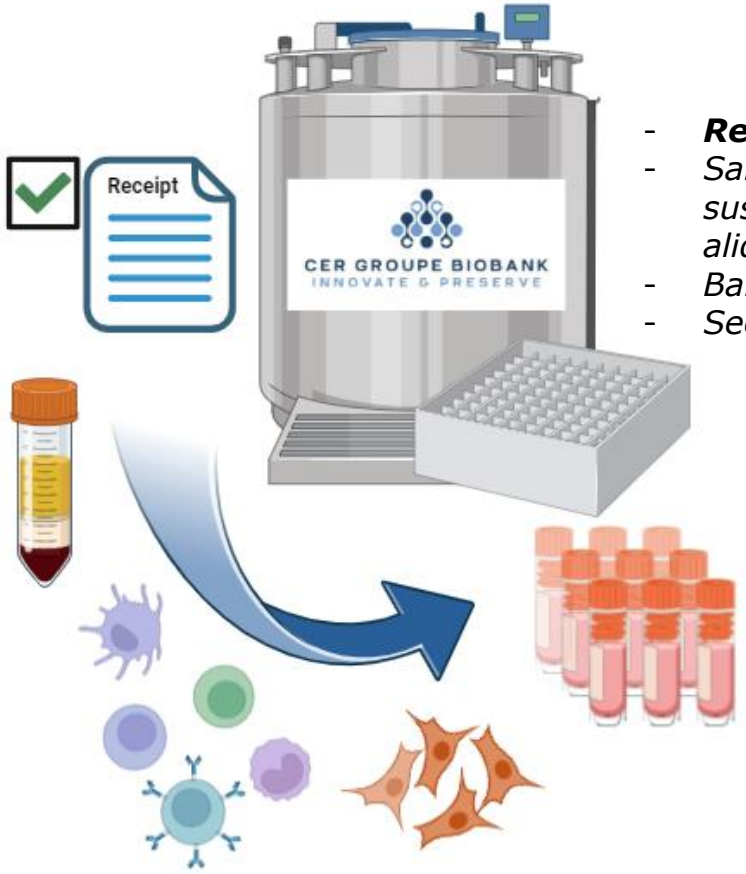


- ***MTA with sender (by CER)***
- ***Contract with sponsor (by CER)***
- *Secured shipment to CER*

CER Groupe

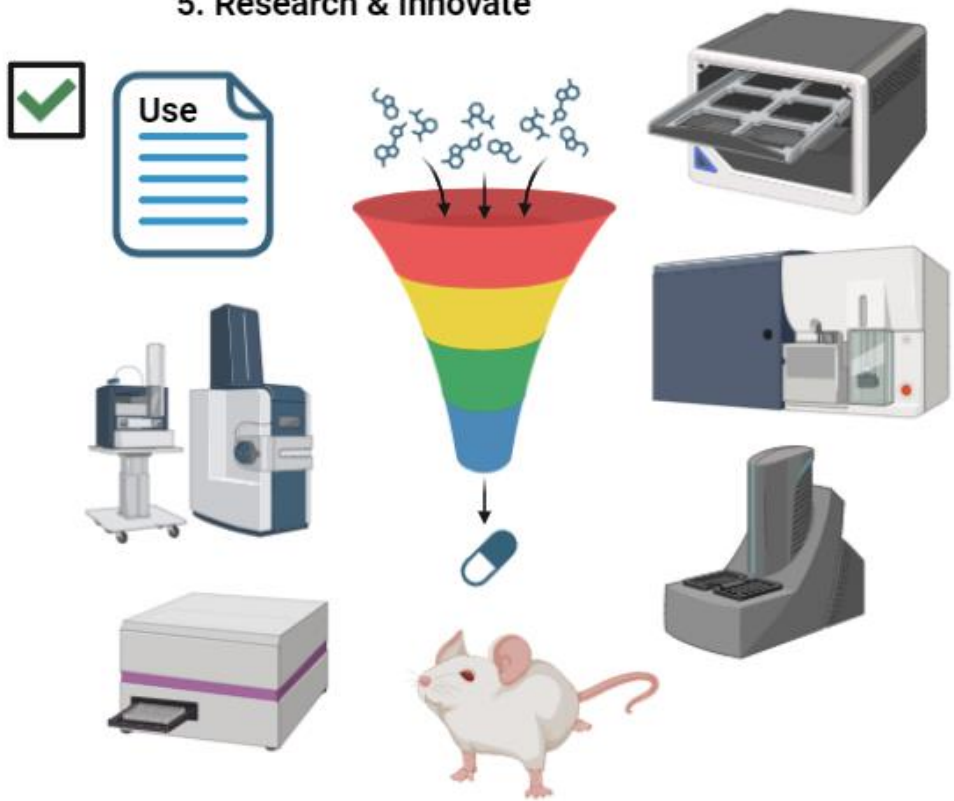
Biobank Services : Innovate & Preserve

4. Reception, preparation and storage



- ***Reception validation (by CER)***
- *Sample preparation (cell suspension, isolation, sorting, aliquoting, …)*
- *Bank constitution*
- *Secured storage (vapor N2, -80°C)*

5. Research & Innovate



- ***Use and destroy sheet (by user)***
- *In vitro testing (PoC, toxicity, ADME, R&D)*
- *In vivo testing*
- *Ab, reagent, kit production*
- *Analytical method validation*

Non-Clinical platform
Our facilities

Surfaces

	Facility	Surface (sqm)
***In vivo* facilities**	SPF	~11000
	BSL-1	~1000
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	BSL-3	~375
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Sheep	40
Goat	40
Pig	60
Cow	80
Horse	2
Llama	25

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Preclinical platform

Discovery

- Proof of Concept (immuno – infection – onco – osteo)
- Small molecules, bioproducts and devices
- Mechanism of action
- Animal Model Development
- Surgery/microsurgery

Preclinical

- Biological samples
- ADME/PK studies
- Safety and toxicology studies
- Bioequivalence
- Residues

QC

- Characterization
- Release (potency *in vitro*)



Non-Clinical platform
Our models

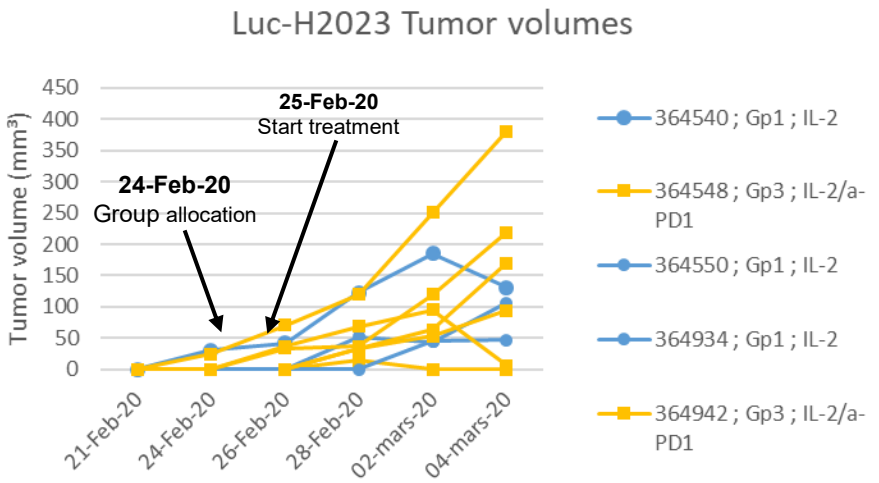
Application	Equipment
Nephrology	Pkd1 (P10, P18, P40)
Neurology	Neurodegenerative diseases
	Neuromuscular diseases
	Psychiatric diseases
	Rare genetic models
	Aging
	Intellectual disability
Oncology	PK
	Spheroids
	PDO
	CDX (syn./xeno.)
	PDX
	Orthotopic/Metastasic models
	Humanized mouse models
Cardiology	Heart failure models
Implantable medical devices	Efficacy models

Application	Equipment
Metabolic	Diabetes (T1, T2, foot diabetic ulcer)
	NIF
	NASH
	ACLF
	Wound healing/thrombolysis
	Intradiscal injection/Pain
Infectiology	Bacteria
	Viruses
	Parasites
	Others
Auto-immunity	Myasthenia gravis
	Allergy/allergenicity (peanut, …)
Musculo-Skeletal	Osteoarthritis (surgery/spont.)
	Rheumatoid arthritis
	Surgery
Pharmacology	Metabolomics
	ADME (incl. ATMP biodistrib.)
	Residues

In vivo cancer models and follow-up

Mouse models	Human models
B16 - Mouse melanoma	HCT116 – Human Colorectal Carcinoma
4T1 – Mouse Mammary Carcinoma	Colo205 – Human Colorectal Carcinoma
PanO2 – Mouse Pancreatic Adenocarcinoma	H2023 – Human Non-Small Cell Lung Adenocarcinoma
CT26 – Mouse Colorectal Carcinoma	A549 – Human Lung Carcinoma
GL261 – Mouse Glioblastoma	PDX models
MC38 – Mouse Colorectal Carcinoma	U87 – Human Glioblastome
Subcutaneous or orthotopic engraftment	





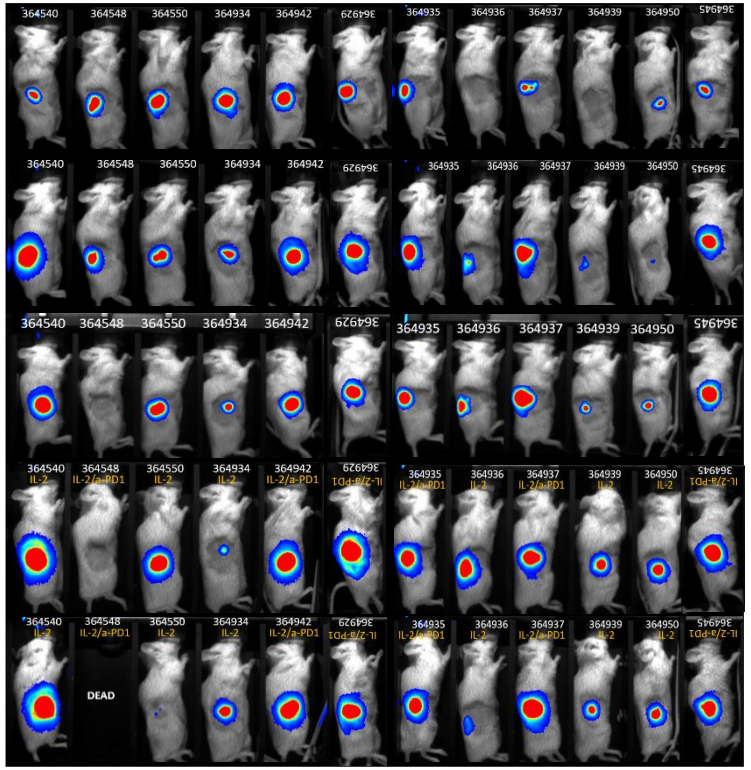
D+7

D+11

D+14

D+18

D+21



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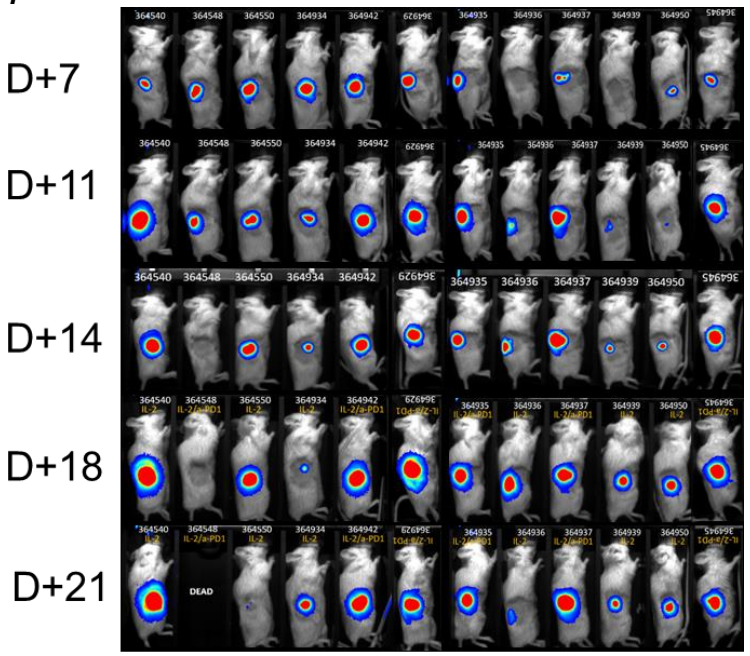
In vivo cancer models in humanized mice

- Mouse humanized by blood cord or fœtal liver
  (Close collaboration with Taconic/Genoway – Certificate of humanization – Short-term replacement of mice with a low human immune system obtained from the same donor)
- Using human cancer cell lines
- Development of humanized PDX models





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Non-Clinical platform - Infectiology models

Family	Agent	Disease	Animal model
Bacteria	*S. aureus*	Mastitis	Bovine, Mouse
	B. abortus bv	Brucellosis	Bovine
	M. tuberculosis bovis	Tuberculosis	Bovine
	M. paratuberculosis	Johne's disease	Bovine
	Salmonella	Salmonellosis	Poultry
Virus	Influenza A	Flu	Small animals
	Neethling	Lumpy skin disease	Bovine
	SPV	Sheeppox	Goat, sheep
	JEV	Japanese encephalytis	Large animal
	IBRV	Infectious Bovine Rhinotracheitis	Bovine
	BVDV	Bovine Viral Diarrhea	Bovine
	H1N1	Pïg flu	Pig
	AIHV-1	Malignant catarrhal fever	Ruminant
	VVM, VAEC	SRLV	Goat, Sheep
	SBV	Schmallenberg	Sheep
	SHV-1	Aujeszky	Pig
	CSFV	Classical swine fever	Pig
	PRRSV	PRRS	Pig
	BTV	Blue tongue	Ruminants
Parasite	Coccidie	Diarrhea	Pig
Others	LPS	Fever	



Non-Clinical platform
Other services relevant for animal health

Pharmacology

Details
In vitro metabolomics
Residues
Immunomonitoring
ADME/PK
Safety
Custom models

Imaging

(for small animals)

Details
µCT scan
Fluo/Biolum. imaging
Echography

Services

Details
Study design
Results interpretation
Statistics (Sigmaplot)
Regulatory support
Archiving

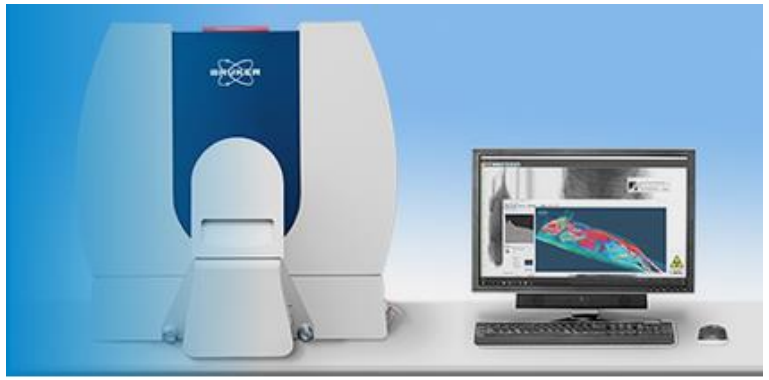
+ Integrated analytical platforms

Preclinical platform – Small animals

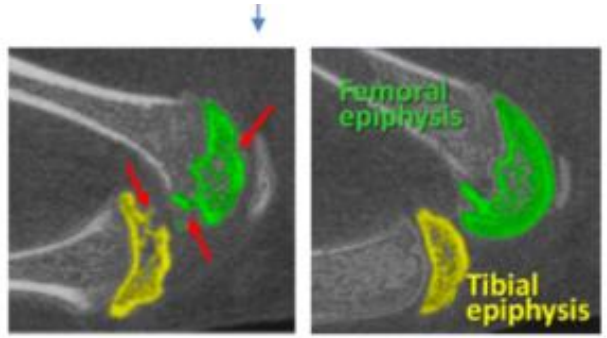
***In vivo* imaging**



Photon Imager Optima

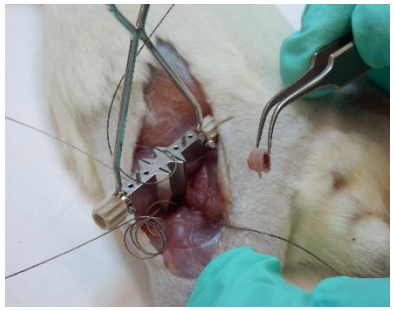


µCT Scan

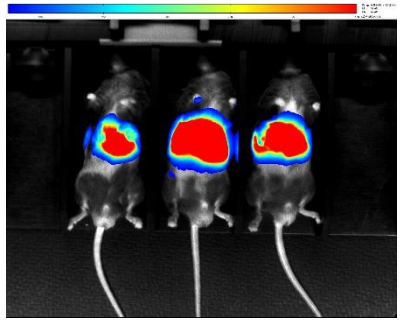


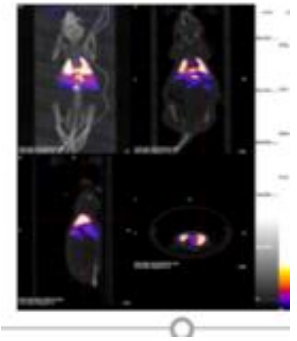
Surgery





Oncology/Gene therapy







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SPF Pigs and Minipigs





Our facility is adapted to house and raise SPF pigs

Pigs are bred in house in or housed for third parties (Transgenic Pigs).

All pens are adapted to the specific needs of each age category and are equipped with suitable environmental enrichment

Multi-species surgery rooms



- ISO Class 3 certified surgery room
- Experimented staff trained in handling small & large animal species (anesthesia, catheterism, surgery, post surgery…)
- Staff available to assist in testing new or minimally invasive surgical techniques
- Testing of novel therapeutics, surgical materials, medical devices (*e.g.* oncology, ophthalmology, cardiovascular or digestive systems)

CER Groupe

PFL s.r.l. Pig For Life

1.3 Collaboration



Why choose us ?



Design
Development
(Pre)Clinical
Batch testing



Efficiency
Agility
Performances
RD/ISO/GLP



Capacities
Facilities
Independence
Track record



Transversal
Veterinary
Food/Feed
Environment



Thank you

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m.benoit@cergroupe.be