



EUROFINS OPTIMED

Global leader in Clinical Trials

1 RUE DES ESSARTS
38610 GIERES - FRANCE



Summary

- EUROFINS World Leader
- EUROFINS Optimed
- Full Services CRO
 - Clinical Pharmacology Unit (Phase I)
 - Multicentric Clinical Trials (Phase I / II)
- Clinical Trials Tools
- Large Therapeutic Areas



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EUROFINS – Key Figures



***World Leader in
Testing for Life***

940
laboratories

€6.7
billion

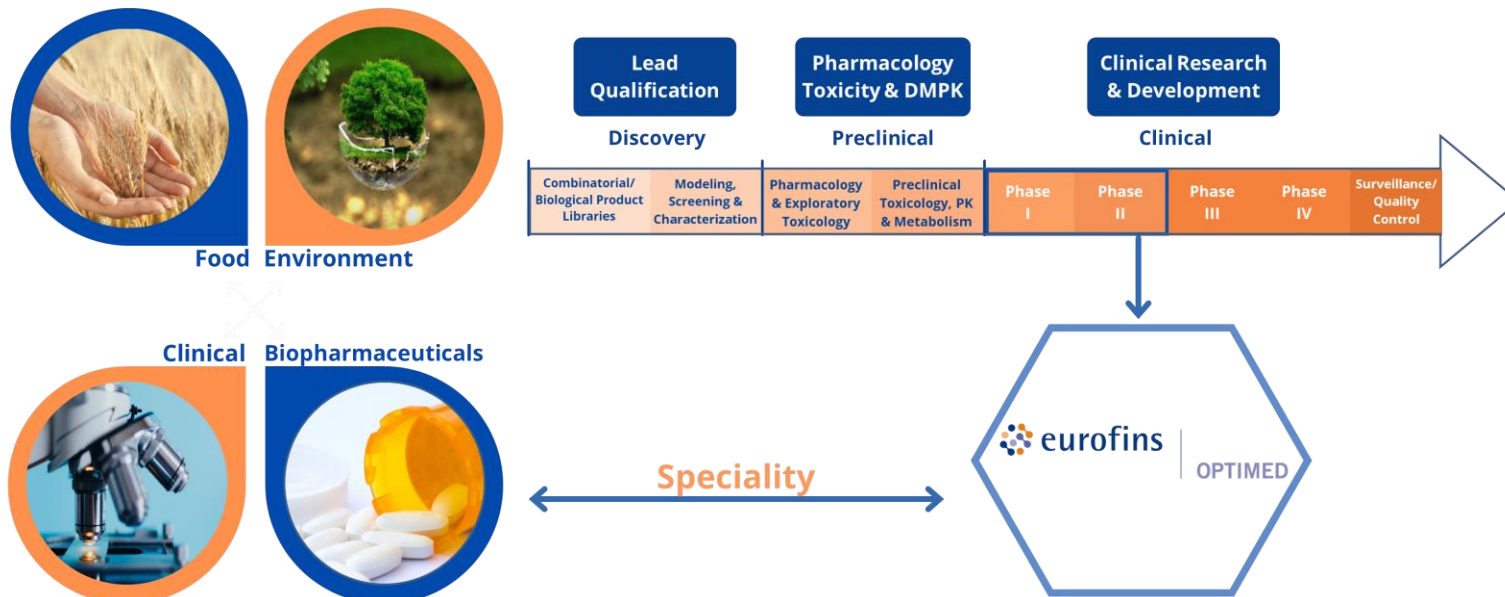
59
active countries

61 000
employees

EUROFINS - Biopharmaceuticals



Eurofins provides testing services in four main areas that have a strong impact on human health:



Early Phase CRO



OPTIMED



Gières – France



CREATED IN 1990

With more than 35 years
of experience



PHASE I UNIT

First in Human



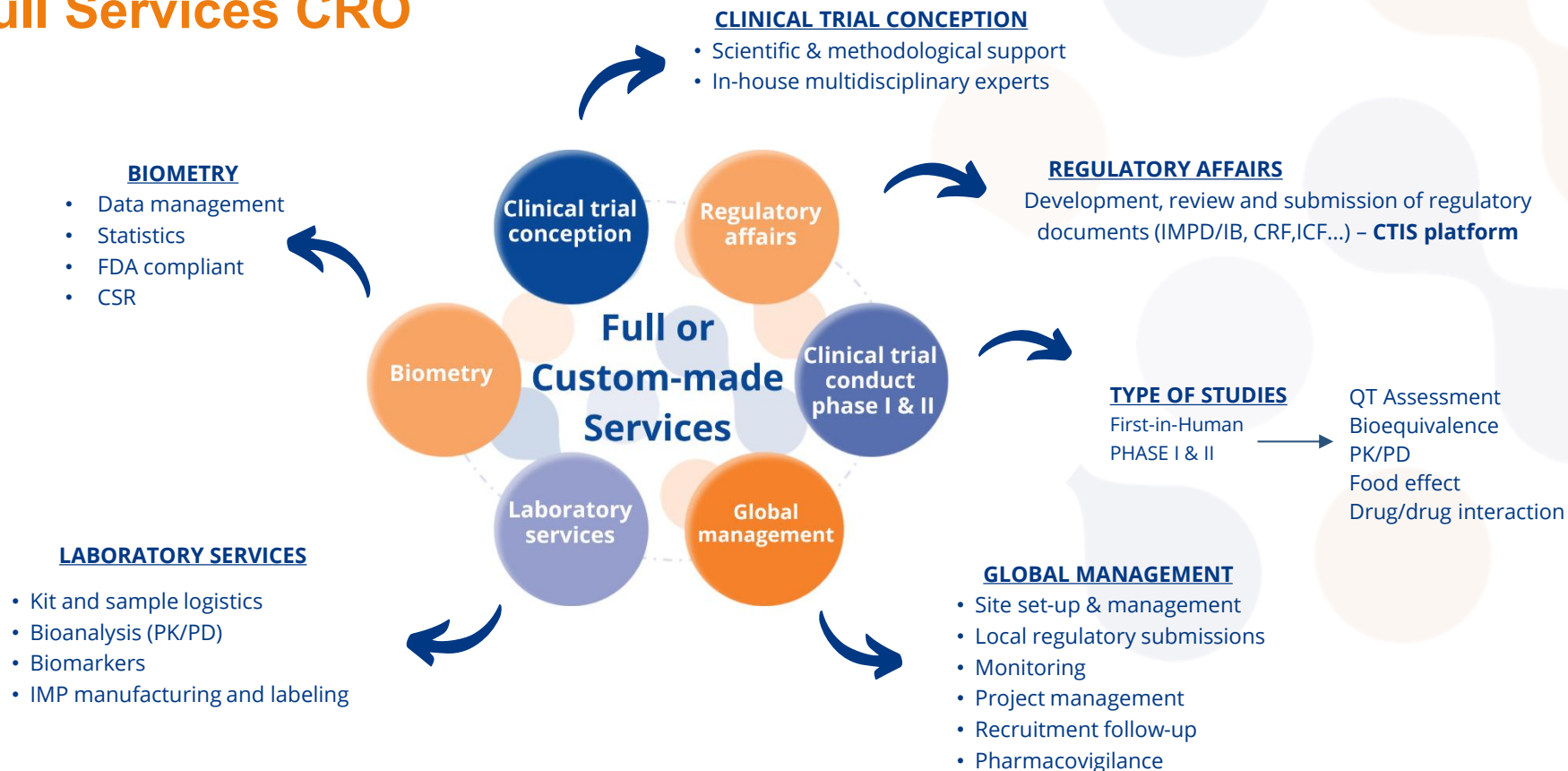
**DRUGS / FOOD /
MEDICAL DEVICES**



FULL-SERVICES CRO

Multicentric international
studies

Full Services CRO



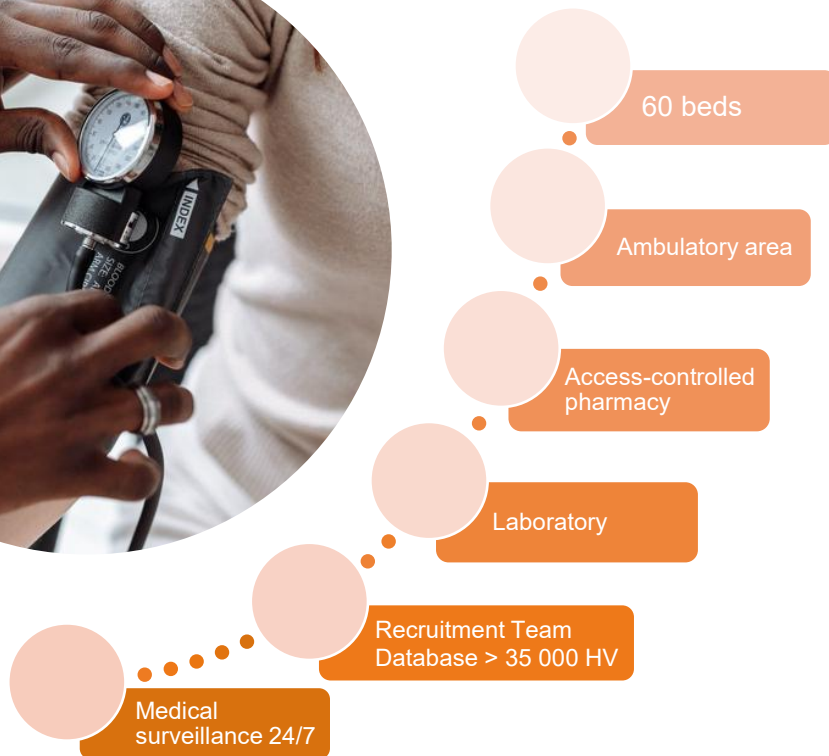
Regulatory Affairs Expertise



REGULATORY SUBMISSION

- ✓ Preclinical protocol & report review
- ✓ Development or review of regulatory documents : IB/IMPD / ICF / CRF
- ✓ Regulatory submission & interaction

Clinical Pharmacology Unit



TYPE OF CLINICAL TRIALS

- First – in – Human (SAD/MAD/FE)
- Bioequivalence / Bioavailability
- Biosimilars
- Drug / Drug interaction
- Pharmacodynamics
- Pharmacokinetics
- QT assessment
- Vaccines



TIMES : Task delegation & Time management

Advanced Unit Equipment

Central Nervous System

- Sleep lab Polysomnography
- EEG standard
- Central EEG analysis
- Psychometric tests
- Pain assessment

Respiratory

- Spirometry
- VO2 max
- DLCO
- Sputum collection

Other Therapeutic Application

- Glycaemic clamp test
- Pupillometry
- Impedancemetry
- VNG
- Ultrasonography
- DEXA Scan



Storage

-200°C Nitrogen / -80°C /
-20°C / 4°C / room T°

Cardiovascular

- Blood pressure monitoring
- ECG monitoring (12-lead / triplicate)
- 24 hours Holter
- Telemetry
- Central ECG reading
- SaO2 monitoring
- Echocardiography

Laboratory capabilities

- PSMII and chemical hoods
- Centrifuges
- Microscope
- PH meters
- Stomacher
- Incubators
- PBMC & Cell count



Customized laboratory techniques

Multicentric Clinical Trials

Eurofins Optimed expertise

- ✓ Up to 1000 volunteers per study
- ✓ 70 investigator sites
- ✓ France, Spain, Portugal, Italy, Germany, Serbia, Finland, Poland, Bulgaria, Czech Republic, Hungary, US, UK, Israel...
- ✓ 30 patient studies over the past 5 years
- ✓ 10 patient studies ongoing



Clinical Trials Competence Centers all over the world

Global Management

Organization

CTIS & Local Regulatory Affairs

Kit and sample logistics

Site set-up and monitoring

IMP packaging and labeling

Recruitment and follow-up

Vigilance

Project Management

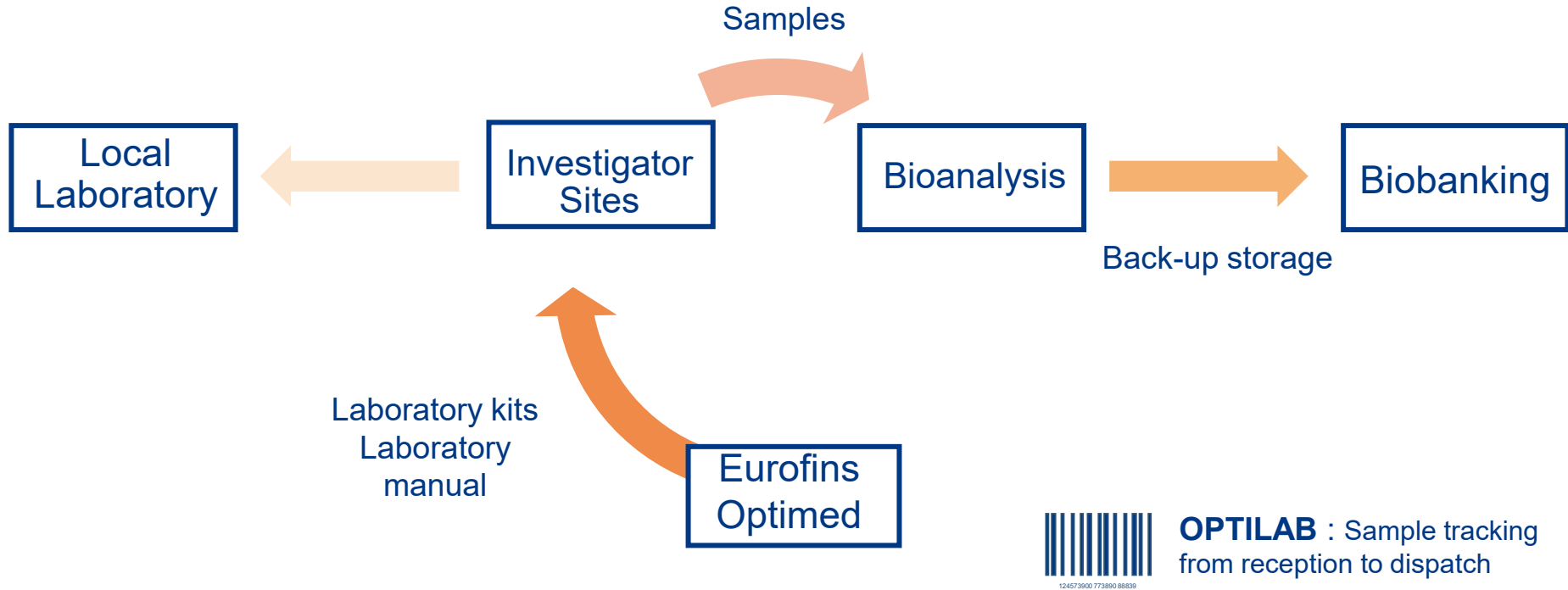
Data management, Statistics,
CDISC conversion & CSR



EUROFINS OPTIMED

Dedicated Project Manager

Sample management and Kit logistics



OPTILAB : Sample tracking
from reception to dispatch

Biometry / Clinical data

Data Management

Study set up

- Kick-off meeting
- Protocol review
- eCRF design and validation
- Writing DMP, DVP, user guide and training

Study conduct

- eCRF management
- External data coordination
- DTS
- Database reconciliation
- Programming
- Technical support
- Medical coding

Study Close out

- SAE reconciliation
- Data management report
- Database Lock
- Archiving

Statistics

- Protocol review
- Randomization List / IWRS
- Statistical Analysis Plan

- Creation of Mock-up tables
- Statistical analysis programming

- TFL generation
- Statistical report writing

CDISC format (FDA compliant)

Clinical Trials - Tools

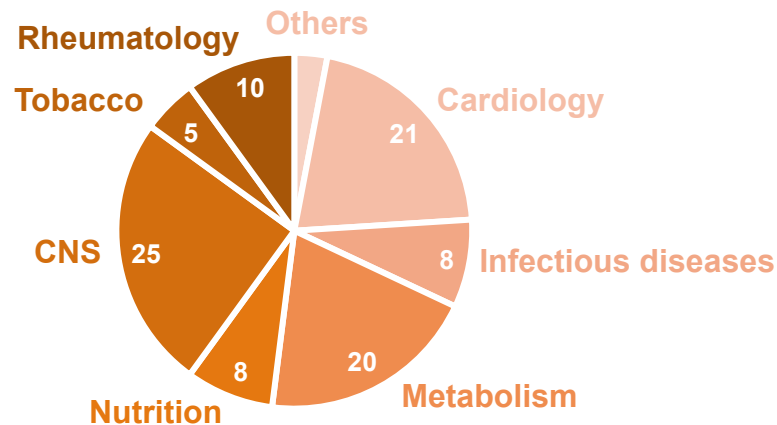
CLINICAL MANAGEMENT TOOLS

The CDISC logo features the word "cdisc" in a bold, blue, sans-serif font. Above the letters "i", "s", and "c" are four small colored dots: red, yellow, green, and blue.The Viedoc logo consists of a stylized orange DNA double helix icon above the word "Viedoc" in a bold, black, sans-serif font.The Ennov logo features the word "eNNOV" in a blue, sans-serif font, with a vertical line separating the "e" from "NNOV". Below it, the tagline "Software for Life" is written in a smaller, grey font.The MedDRA logo features a circular icon with a green and blue design, representing a globe or a stylized 'M'. Below the icon, the word "MedDRA" is written in a bold, blue, sans-serif font.The Uppsala Monitoring Centre logo features a stylized green and blue icon representing a waveform or a stylized 'M'. Below it, the text "Uppsala Monitoring Centre" is written in a small, grey font.The WHODrug logo features the word "WHODrug" in a bold, purple, sans-serif font. Below it, the text "User area" is written in a smaller, grey font.

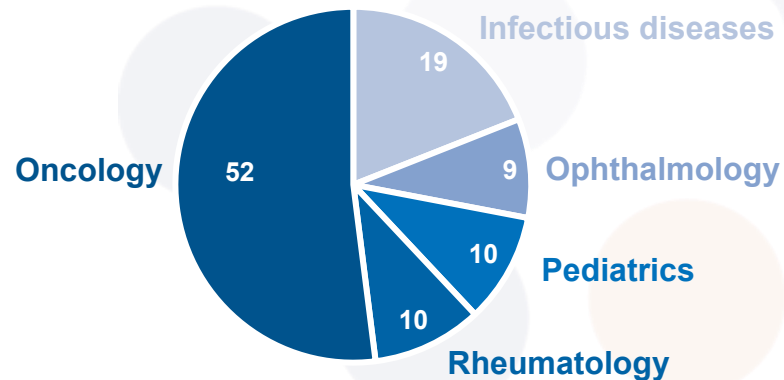
- Clinical Study Report : eCTD Format
- CDISC format : FDA compliance
- EDC : *Ennov Clinical* or *Viedoc*
- eTMF : *Viedoc*
- Medical Coding : *WHODrug* & *MedDRA*
- Optilab : Sample tracking
- Times : Task delegation & Time management
- CTMS

Large Therapeutic Areas (%)

Healthy volunteers



Early development in patients



Conclusion - 35 years of expertise



Human scale CRO

Flexibility, agility, rapid decision-making



Project success

Strong corporate culture and commitment to project success



Expertise

Strong medical and regulatory expertise in several therapeutic areas



Project management

Easier communication, excellent cooperation with our partners



Global management

International clinical trials management, strong investigator network

Thank you for your attention



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