GCLP (Good Clinical Laboratory Practice) certification for clinical studies and trials.

GCLP certification is required by the AIFA regulations (AIFA Determination No. 809/2015) to ensure that clinical chemistry activities carried out in clinical trials (from Phase I to Phase III) are performed in accordance with the standards required by international regulatory agencies, under the recommendations of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. IRET has acquired this standard, starting with immunological assays, which are biochemical methodologies allowing the presence of a substance to be detected through its recognition by an antibody. IRET has developed twenty years of experience in the use of these methods and in recent years it has made this expertise available to external public and private entities. Investments in equipment in recent years have also made it possible for IRET to use all variations of these applications.

"GCLP certification in support of clinical trials."

Laboratory	IRET
Specialization Area	Health and Wellness
Contacts	Maura Cescatti
Keyword	GCLP (Good Clinical Laboratory Practice) , Immunological essay , Clinical research



Fig. 1: IRET Foundation, managing body of the Bologna-Ozzano "Rita Levi-Montalcini" Technopole

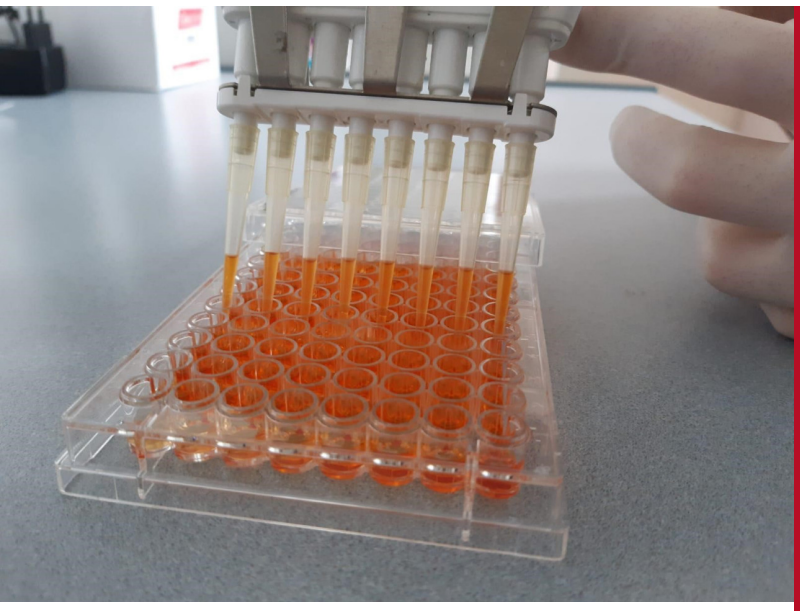


Fig. 2: Preparation phase of a plate for a colorimetric immunoenzymatic assay.

Description

Immunological assays are widely used in both research and clinical practice, but it is necessary to select the appropriate method for the biological problem being investigated, use the appropriate equipment, and interpret the results. However, the application of these assays in controlled clinical trials is only possible with GCLP certification.
IRET offers a service that includes the following steps:

1. Analysis of the experimental problem and identification of the most appropriate technological solution. IRET's equipment allows for the application of colorimetric, fluorescent, and chemiluminescent assays.
2. Performance of the analysis.
3. Transmission of results.
4. Support for the analysis of results.

IRET meets the requirements necessary to use these assays in clinical studies:

• Authorization to carry out healthcare activities issued by the municipality of Ozzano Emilia on the basis of a favorable opinion expressed by the competent local health authority (Protocol No. 0014287);
• Certificate of compliance with the principles of Good Laboratory Practice (Legislative Decree No. 50 of March 2, 2007 – Directive 2004/9/EC);
• Inclusion in the list of Phase I Self-Certified Facilities pursuant to AIFA Resolution No. 809/2015 (facility code FI/319);
• Guidelines and procedures for privacy in the management of biological samples of human origin.

Innovative aspects

The development of biotechnologies since the 1980s and 1990s has radically changed the field of pharmacology. On the one hand, biotechnology has paved the way for the synthesis of complex biological molecules, while on the other, the development of molecular biology has made it possible to understand and intervene in the events underlying the genesis of numerous diseases. The focus on drug delivery has also extended the use of these new skills to the pharmacokinetic aspects of the therapeutic process.
The increasing complexity of molecules has inevitably led to an increase in the complexity of the methods used to study them.

The multidisciplinary approach and possession of the required regulatory requirements have allowed IRET to adapt traditional routine methods to specific objectives, addressing the complexity that this technological evolution has brought to all aspects of drug research and development.

Potential applications

The applications developed thus far concern:
1. Support for clinical research starting from the validation of the method according to the EMA ICH M10 guideline on bioanalytical method validation - Scientific guideline;
2. Dosages of specific analytes for Phase I/II clinical trials (pharmacokinetics);
3. Assay services for institutions that do not have adequate instrumentation;
4. Support for academic research.

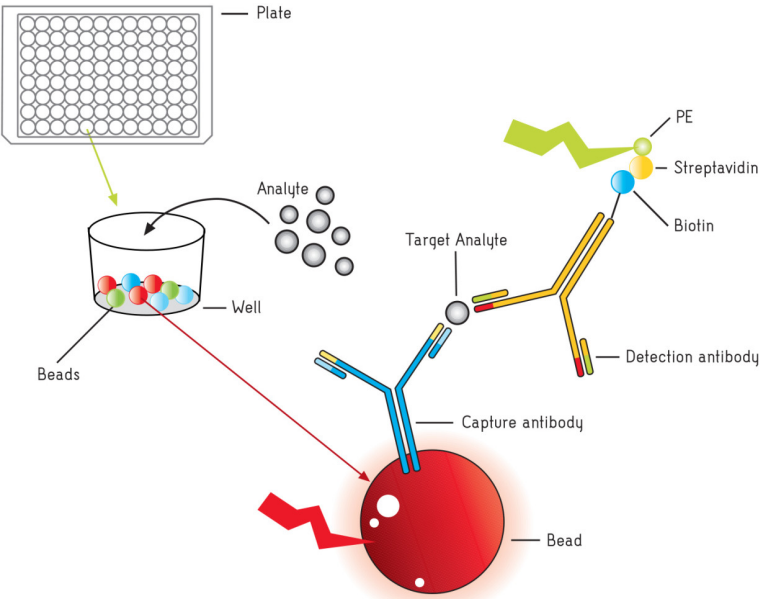


Fig. 3: Schematic representation of the principle underlying xMAP technology, which was used for the assays performed in the clinical trials of the application described.

Involved partners	Pharmaceutical/biotechnology companies
Implementation Time	Method validation according to GCLP: 60 days
Technology Readiness Level	TRL8 - System complete and qualified
Exploitation	Combining research expertise and routine analytical services in a single partner allows us to: - address critical aspects of the process that could compromise results with flexibility and speed; - in the most technologically mature phases, complete the process entirely within the territory, as described in the objectives of the EU STEP action (Biological medicines).

Application example

The service described above can be applied to various areas of translational and pharmacological research. It allows companies in the pharmaceutical/biotechnology sector to interact with a single partner from the R&D phase through to clinical trials (TRL 5 to 8). It offers research institutions a ready-to-use service.

IRET was involved by companies in the pharmaceutical/biotechnology sector at the beginning of the R&D process for protein-based drugs. In these initial stages, the companies were supported in defining the efficacy of the molecule, thanks to the use of animal disease models. In these early stages, *in vivo* and *in vitro* toxicology studies were also integrated with efficacy studies, and the foundations were laid for the development of analytical methods to be used in subsequent clinical pharmacokinetic studies.
Once the efficacy of the drug had been demonstrated and the correct method of administration selected, the technical aspects of dosing were investigated in depth. They were applied to the specific clinical applications envisaged and the methods were validated according to the EMA guideline “ICH M10 on bioanalytical method validation.”

Following the validation of the method, IRET was involved in Phase I and I/II clinical trials, producing the data necessary for the pharmacokinetic characterization of the new molecules.
After the conclusion of the clinical trials, the same drugs and methods were reused for different therapeutic purposes or for dosages in different biological fluids. IRET was involved again, allowing the company to avoid starting from scratch in the drug repositioning process, saving time and resources.

IRET

FONDAZIONE IRET - L'OCCHIO DELLA CONOSCENZA SUL CERVELLO - ETS



IRET Foundation is a scientific research organization in the biomedical field, dedicated to the study of diseases “without cure” such as degenerative diseases and injuries of the central nervous system (multiple sclerosis, Alzheimer’s dementia, vascular dementias, ataxias, Parkinson’s disease, traumatic injuries and vascular lesions of the brain and spinal cord, chronic pain). It conducts research in the areas of neurology, rare and dysmetabolic diseases, regenerative medicine, drug discovery, development and screening, advanced therapies, and tissue engineering.
IRET has extensive experience in modeling *in vitro* (cell lines, primary cells, and stem cells cultured with 2D and 3D techniques) and *in vivo* (transgenic animals, surgically induced lesions, chemical, immunological). The research carried out aims to identify innovative strategies to counteract the progression of diseases, repair their damage, and identify causes to prevent their occurrence.
It has a large facility for animal experimentation (rats and mice), equipped with an operating room and laboratories for the study of complex behaviors; laboratories for cell cultures, molecular biology, proteomics. It has a major facility for advanced microscopy and computerized image analysis in 2D, 3D, 4D.
The IRET Foundation has signed research collaboration agreements with several departments of the University of Bologna and Ferrara and with hospitals in the Region. IRET also has agreements with the Montecatone Rehabilitation Institute in Imola and the ISMETT Institute/Ri.MED Foundation in Palermo.
The IRET Foundation is the Ozzano dell’Emilia branch of the Bologna Technopole named after Rita Levi-Montalcini.

Website http://iret-foundation.org/

Director Luciana Giardino

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