oncodesign services

A best integrated solution for your IND-enabling studies package

Oncodesign Services provides, with the support of dedicated partners for the GLP in-life phase, non-GLP and GLP studies to assess the safety of your medicine.

PRECLINICAL TOXICOLOGY STUDIES

Toxicology studies provide essential data on the potential safety and toxicity of a drug candidate, prior to First-In-Human (FIH) administration.

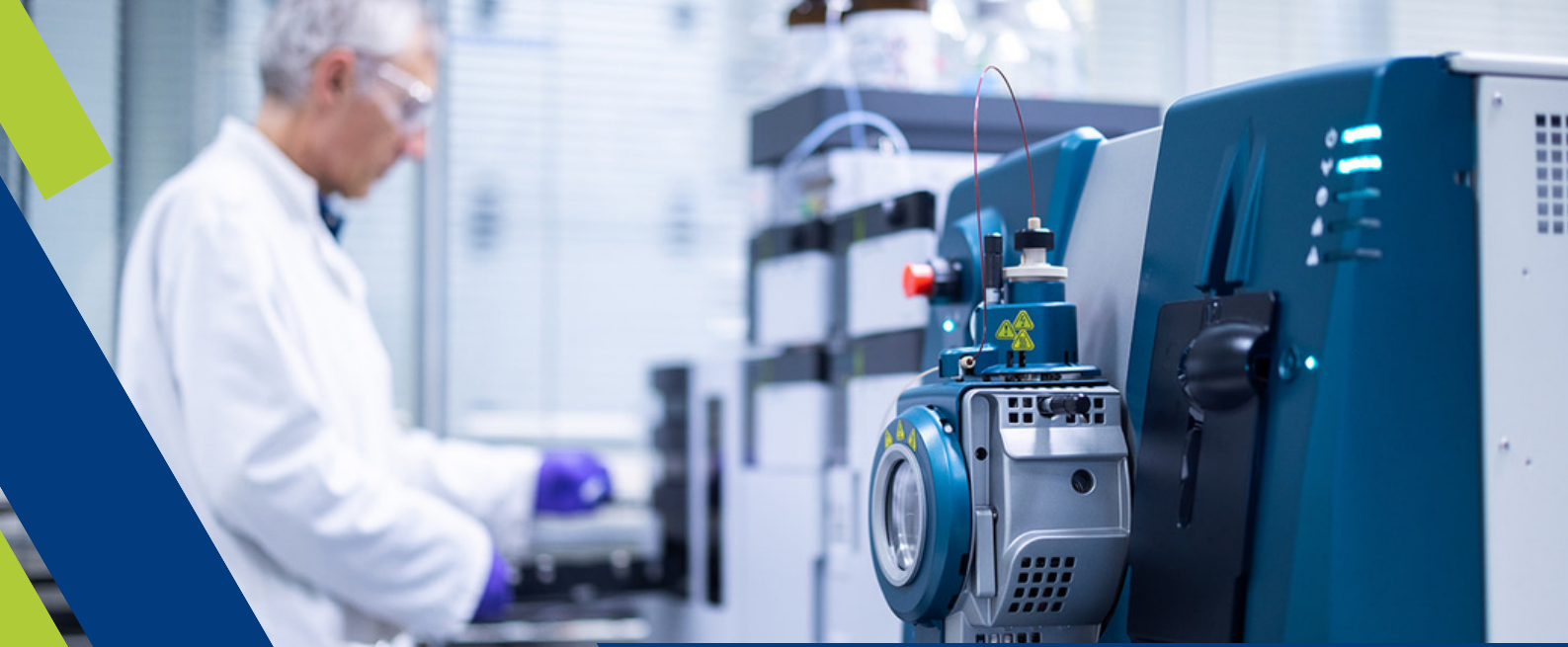
Oncodesign Services has the capabilities to move a step forward your Pre-Clinical Candidate to the **US IND** (Investigational New Drug) or to the **European IMPD** (Investigational Medicinal Product Dossier) by providing guidance in building the right IND enabling studies package.

Moreover, early regulatory engagement with Health Authorities (HA) such as EMA/FDA is always recommended.

Regardless of the therapeutic modality or new therapeutic entity (NTE), Oncodesign Services has the expertise to provide you insights regarding the building of IND enabling studies package for **NBE** or **NCE**. Such package is completely customizable following your scientific and regulatory inputs.

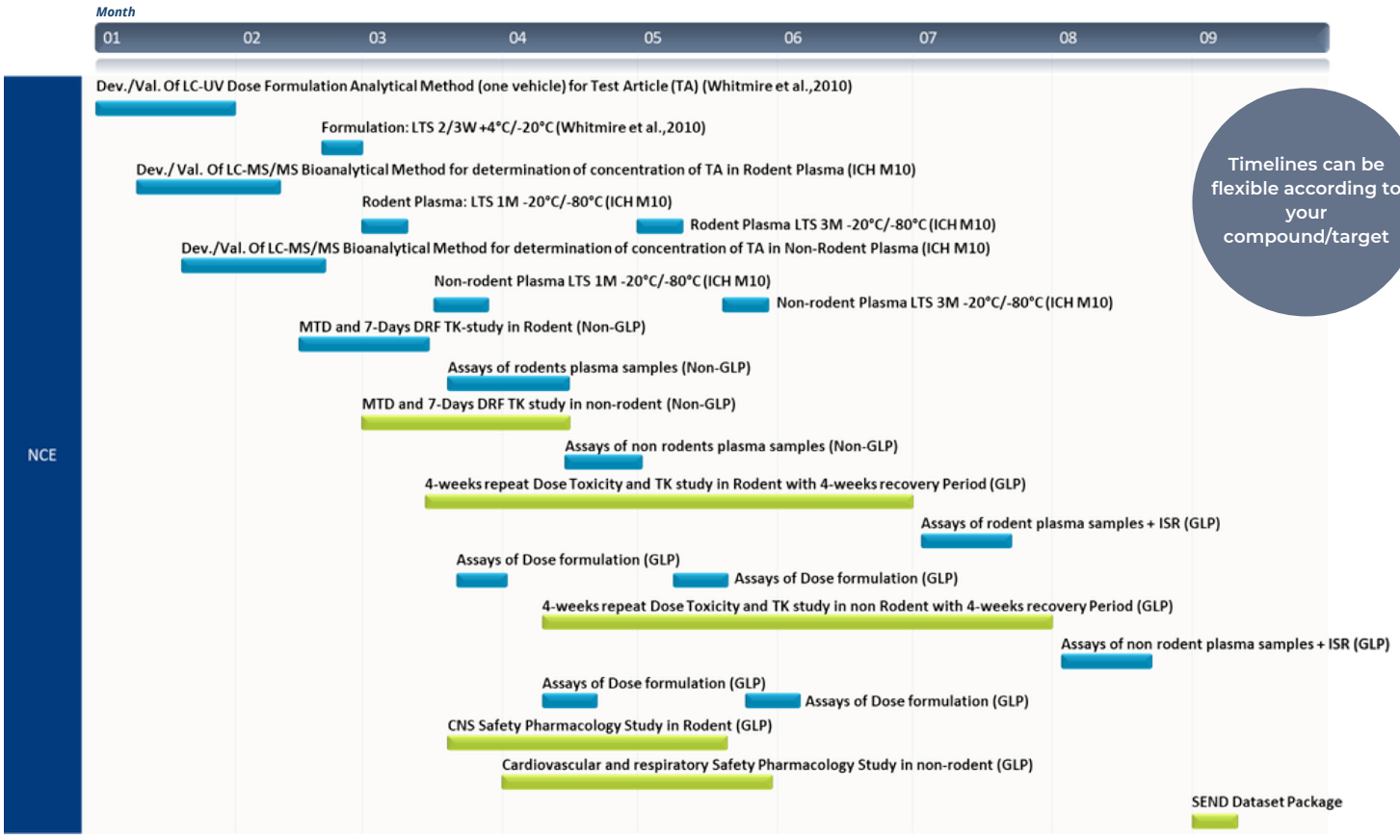
OUR SERVICES

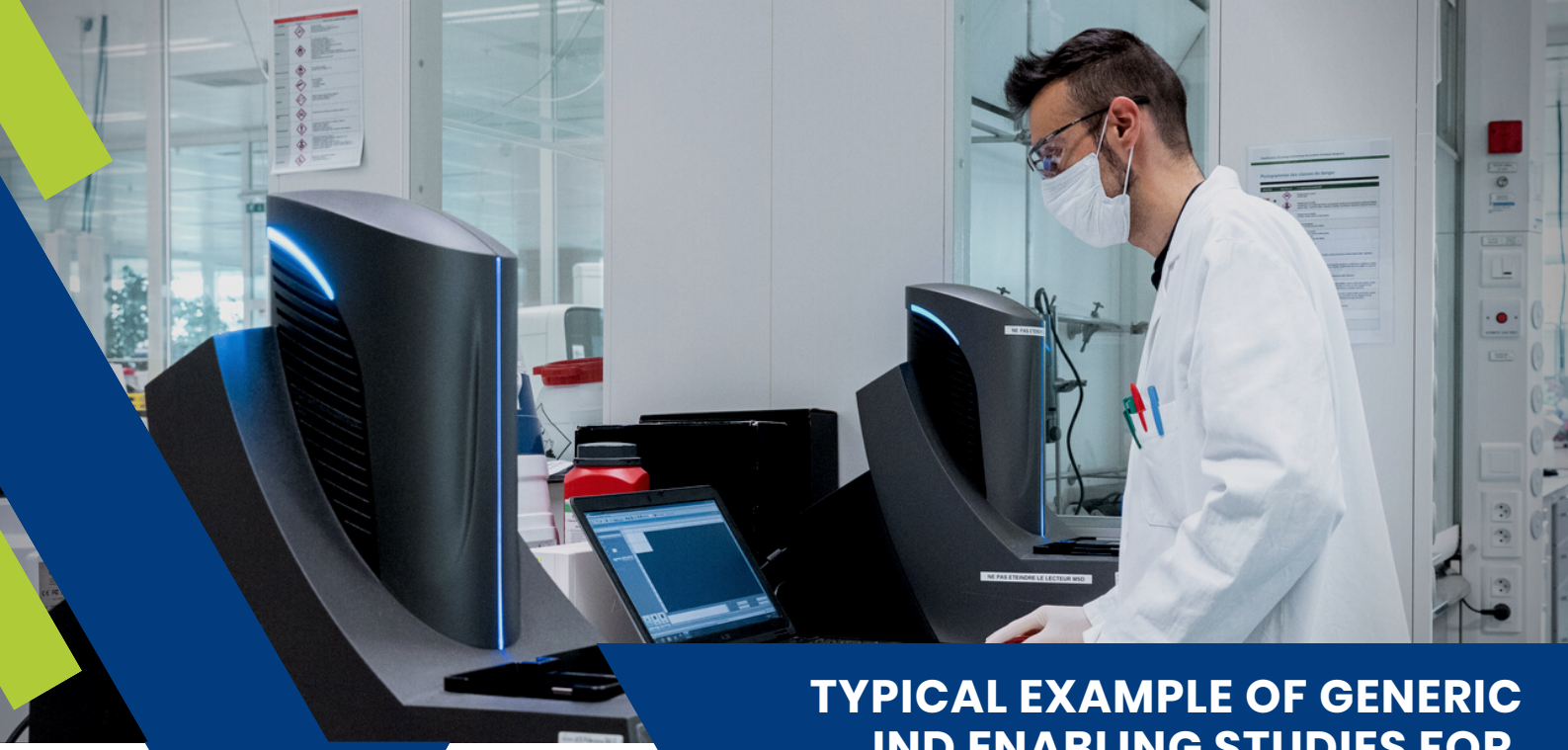
- Development and validation of analytical method for formulation
- Dose formulation analysis (GLP)
- Development and validation of bioanalytical method (ICH M10)
- Development and validation of ADA screening method
- *In vivo* toxicology



TYPICAL EXAMPLE OF GENERIC IND ENABLING STUDIES FOR NEW CHEMICAL ENTITIES (NCE)

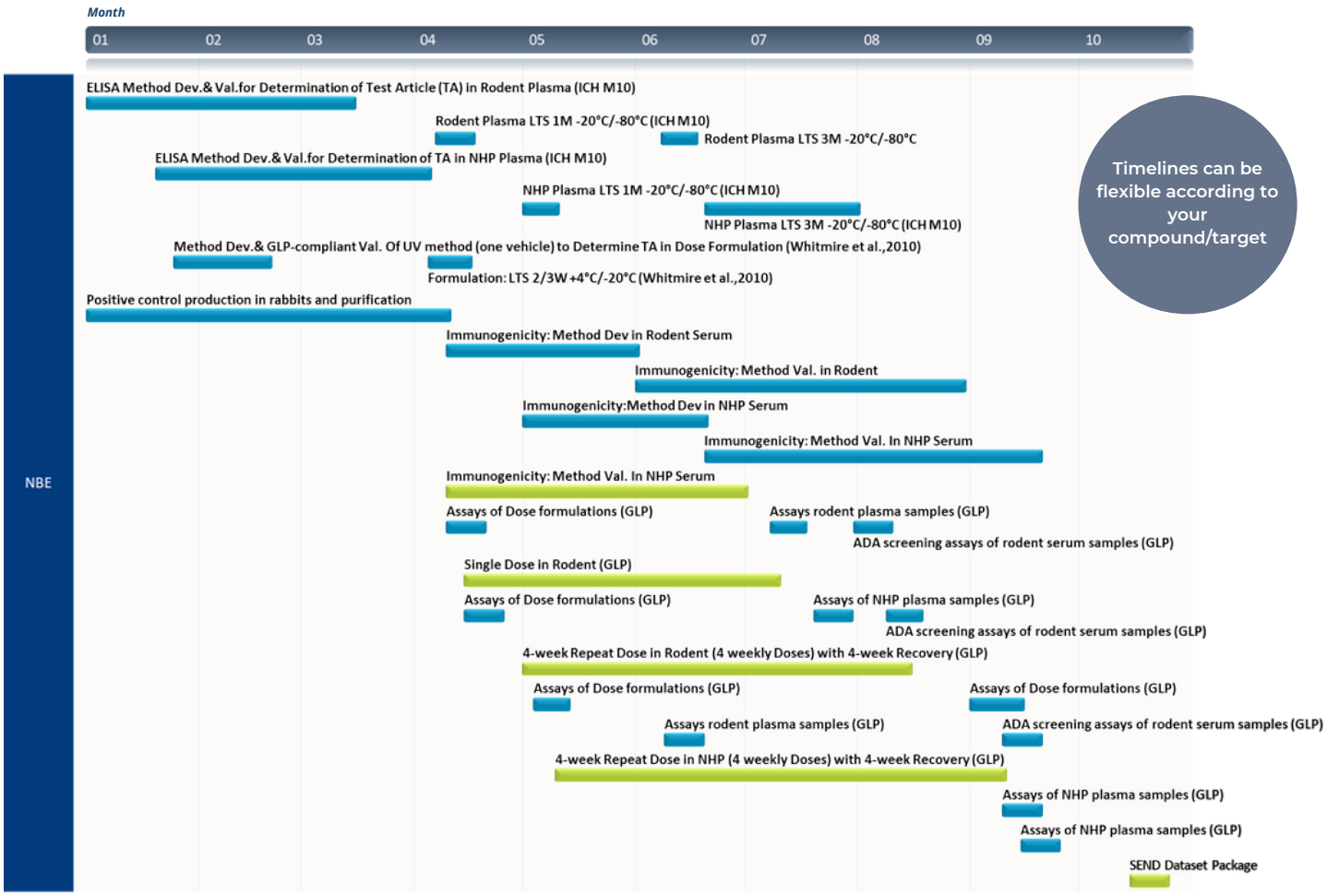
Considering that clinical relevance is the driving force for a non-clinical program, the generic example below for NCE is based on regulatory applications being made within Europe or USA; rest of World has not been taken into consideration.





TYPICAL EXAMPLE OF GENERIC IND ENABLING STUDIES FOR NEW BIOLOGICAL ENTITIES (NBE)

This generic example is based on regulatory applications being made within Europe or USA only. All bioanalytical/formulation/immunogenicity/biomarkers will be taken over by Oncodesign Services in our GLP test facility site at Paris Saclay (France). The other parts of studies (mostly GLP in life phases) will be subcontracted to dedicated partners.



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Oncodesign Services is a Contract Research Organization (CRO) specializing in drug discovery and preclinical services.

From target identification to IND filing, the company contributes to the development of innovative therapies in oncology, inflammation and infectious diseases, where there is unmet medical needs for patients.

CONTACT US

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